HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING SEPTEMBER 24, 2014 APPLICATION SUMMARY

NAME OF PROJECT:

Coram Alternate Site Services, d/b/a CVS/Specialty

Infusion Services

PROJECT NUMBER:

CN1406-018

ADDRESS:

1680 Century Center Parkway, Suite 12

Memphis, (Shelby County), Tennessee 38134

LEGAL OWNER:

Coram Specialty Infusion Services, Inc.

555 17th Street, Suite 1500

Denver, (Denver County), Colorado 80202

OPERATING ENTITY:

Not Applicable

CONTACT PERSON:

Alex Coulter Cross

Harwell, Howard, Hyne, Gabbert and Manner

333 Commerce Street, Suite 1500

Nashville (Davidson County), Tennessee 37201

(615) 251-1047

DATE FILED:

June 6, 2014

PROJECT COST:

\$98,000

FINANCING:

Cash Reserves

PURPOSE FOR FILING:

Establishment of a home care organization and the initiation of home health services limited to provision and administration only of home infusion products and related nursing services ancillary to its pharmacy

DESCRIPTION:

Coram Alternate Site Services is requesting approval to establish a home care organization and initiate home health services limited to providing and administering home infusion products and related infusion nursing services ancillary to its pharmacy services in a 25 county area in West Tennessee. If approved, the applicant plans to operate from its licensed home infusion pharmacy, which is located at 1680 Century Center Parkway, Suite 12 Memphis, (Shelby County), Tennessee 38134

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

HOME HEALTH SERVICES

- 1. The need for home health agencies/services shall be determined on a county by county basis.
- 2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.
 - The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.
- 3. Using recognized population sources, projections for four years into the future will be used.
- 4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

Following Steps 1-4 above the Department of Health report that is based on 2013 data, indicates that 24,903 service area residents will need home health care in 2018; however 42,322 patients are projected to be served in 2018 resulting in a net excess of (17,419).

It appears that this application does <u>not</u> *meet the criterion.*

- 5. Documentation from referral sources:
 - a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

The applicant provided 1 letter (located in Attachment C, Home Health Services) from a physician in the Memphis (Shelby County) area. The letter was written on Coram letterhead so it is unknown whether this physician is an employee of Coram or will be a future referral source. No indication is given regarding the potential number of referrals.

Since the applicant is requesting a 25 county service area, it appears that this criterion may be only partially met.

The applicant notes 100% of the 207 cases in Year One will consist of infusion related skilled nursing home health visits. A table listing skilled home health patients by infusion therapy type in Years 1 and 2 was provided in Supplemental 2. However, as previously noted, the 1 physician referral letter did not specify the number of potential referrals.

It appears this criterion may only be partially met.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant included 9 letters in Attachment C, Home Health Services. Only 4 of the 9 letters were pertinent to this application. The other 5 were pertinent to the East Tennessee Coram application that is also being heard on this same agenda. However, as previously indicated, the physician letter did not indicate the number of potential referrals nor that the physician had been unable to find appropriate services. There was also one letter from a potential patient that is relevant to this application (Germantown in Shelby County). Both the physician and patient letters

focus on the difficulty in locating a proficient home health provider specialized in infusion nursing services.

Since the applicant is requesting a 25-county service area, it appears that this criterion may be only partially met.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

Coram does want to provide services different from a typical home health agency in that it wants to limit its services to home infusion related services. The infusion services would be provided by a CRNI (certified registered nurse infusion). The applicant claims these services and credentials are unique and are not typical of the average Medicare certified home health agency.

It appears this criterion may be met.

- 6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
 - a. The average cost per visit by service category shall be listed.

The average cost per skilled nursing visit for the applicant is projected to be \$133.00 in Year One, as compared to an average of \$111.00 for a visit in 2013 of other home health agencies in the proposed service area. The applicant states that the reason for the applicant's higher cost is due to the longer length of specialty infusion cases which typically last from 5 to 6 hours. A Table on page 59 lists skilled home health visit costs comparisons with service area home health agencies.

It appears this criterion <u>has been met.</u>

b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The applicant projects to serve 207 patients in Year One. The applicant's projected average cost per patient will be \$1,140.46.

It appears this criterion has been met.

Staff Summary

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Summary

The proposed home health agency will be located adjacent to the applicant's infusion pharmacy. The payor types of home health patients to be served by the applicant will be privately insured, self-pay, or medically indigent patients under the age of 65 who do not qualify for Medicare and Medicaid services. The applicant does not intend to certify its limited service home health agency for Medicare and Medicaid.

The applicant will on occasion provide services to Medicare and TennCare infusion patients. The applicant will either bill those patients at the applicant's self-pay rate for a private nursing visit, or if the patient qualifies apply the visit to the applicant's charity care and bad debt policy.

The applicant's pharmacy is licensed by the State of Tennessee and is Joint Commission Accredited. The pharmacy participates in both Medicare and TennCare and also serves medically indigent patients.

In addition to infusion services, Coram Specialty Infusion Services would provide additional infusion-related services such as line maintenance, phlebotomy services, infusion equipment repair and replacement, and dressing changes on central lines and external access ports. These services will be provided by a registered nurse who is appropriately credentialed and is certified with a certified registered nurse infusion (CRNI) designation. The infusion product will be compounded at the applicant's licensed pharmacy and taken by secure courier to the patient's home where it will be met by the infusion nurse Types of infusion products to be administered include: for administration. antibiotics; total parenteral nutrition (TPN); hydration; cardiac products (such as inotropic therapies); intravenous immunoglobulin (IVIG) and other similar specialty drugs; pain management; antiemetic; and steroids. The types of patients served by Coram who have demonstrated needs for infusion nursing services in the home which are otherwise unavailable from other home health agencies include the following:

• Specialty Patients Requiring IVIG -Intravenous immunoglobulin is given as a plasma protein replacement therapy for immune deficient patients who have decreased or abolished antibody production capabilities.

- Alpha 1 Therapies-Alpha -1 antitrypsin infusion therapy is given to treat the genetic disorder alpha-1 antitrypsin deficiency that causes defective production of the alpha-1 antitrypsin (A1AT) leading to decreased A1AT in the blood and lungs.
- First Dose Administration-First time a prescribed infusion therapy is provided to a patient.
- Low Intervention Patients-Patient who are not homebound and do not require significant intervention; they are taught to self-administer thereby limiting the number of home skilled nursing visits.
- Three Dose Schedule Patients-Infusion therapy patients whose therapy is administered three times throughout a day.
- Rural Patients-Patients living outside urban areas where there is an abundance of major medical centers and infusion centers
- Pediatric Patients-Children requiring infusion therapy products and services.

The applicant states that the types of patients requiring these infusion services include patients with compromised immune system or auto immune disorders, transplant patients, congestive heart failure patients, patients who cannot consume nutrition or food via regular intake, hemophiliacs or patients with other blood clotting disorders, patients with progressive emphysema, and other conditions.

Ownership

The applicant is a wholly owned subsidiary of Coram Specialty Infusion Services, Inc., which has as its ultimate parent CVS Caremark Corporation, also a Delaware corporation. The applicant owns 3 pharmacy branches in the state located in the cities of Memphis, Nashville, and Knoxville. The applicant has a home health agency limited to infusion services based in Nashville with a licensed service area of 38 middle Tennessee counties.

Facility Information

- The proposed project will be part of existing leased space consisting of 6,766 square feet of office space
- The current office space includes a pharmacy, distribution warehouse and administrative offices and support space.
- There is no construction, renovation or modification required to implement the proposed project.

Project Need

- The applicant indicates general home health agencies do not typically provide the following services that the applicant proposes to provide: 1) therapies in excess of three hours, 2) infuse blood or blood products in the home, 3) take on patients that are not homebound and do not qualify for Medicare reimbursement, 4) provide first dose administration, 5) staff for patients needing 3 doses a day every eight hours, and 6) provide infusion services to pediatric patients and to patients residing in rural areas.
- Discharged hospital patients requiring infusion nursing services either have to travel to the hospital or infusion therapy centers to continue receiving this service. These patients also risk exposure of their immune suppressed bodies to nosocomial infections.
- Patient having first dose infusion services at home may reduce length of stay at the hospital.
- The applicant performed a service area study that had several components. One component was a profile of a typical Medicare-certified home health agency patient and infusion therapy patient, which is summarized in the chart below:

Variable	Medicare Home Health Agency	Infusion Nursing Agency		
Average Visit Duration	One to Two Hours	Up to six hours		
Equipment	Generally not involved Typically includes infu			
Payor	80% Medicare and TennCare Patients	Private Insurance mainly		
Age	Approximately 68% Over Age 65+	Predominately under Age 65		
Service Provided	44% is skilled nursing. Balance of service includes therapy, home health aide, and medical social services.	100% specialized skilled nursing		
Patient Status	Homebound	*Patient may or may not be homebound		

^{*}Applicant states that a non-homebound patient may not have reasonable geographic or financial access to reach an ambulatory infusion center, hospital, or other venue for infusion. The applicant also states that home infusion therapy is more cost effective than infusion in an institutional setting.

- The study also included a survey of area home health agencies regarding their availability for infusion services for several scenarios. The applicant received 46 agency responses which in general indicated that at least 50% indicated that they did not provide infusion services, approximately one-third indicating they would provide the service if they had the staff, leaving a handful of agencies indicating that they could provide the service. In the case of first dose administration, 87% of the agencies indicated that they did not provide the service.
- The study also included individual patient profiles (patients identified as patient A, Patient B, etc.) indicating hardship in locating an agency to provide their infusion services and the agencies that declined to provide the service.
- To see the details of this service area study, see pages 31-44 of the original application.

• Note to Agency members: The Department of Health Report indicated that based on 2013 data, 24,903 service area residents will need home health care in 2018; however 42,322 patients are projected to be served in 2018 resulting in a net excess of (17,419). Please note that this need is calculated for all home health patients, not just those needing home infusion services.

Service Area Demographics

- The total population of the 25 county service area is estimated at 1,637,554 residents in calendar year (CY) 2014 increasing by approximately 1.4% to 1,660,453 residents in CY 2018.
- The overall statewide population is projected to grow by 3.7% from 2014 to 2018.
- The 65 and under population will decrease 0.4% from 1,412,739 in 2014 to 1,407,623 in 2018. The statewide 65 and under population will increase from 2.2% between 2014 and 2018.
- The latest 2014 percentage of the service area population enrolled in the TennCare program is approximately 22.7%, as compared to the statewide enrollment proportion of 18.1%.

Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics, U.S. Census Bureau, Bureau of TennCare.

The 25 counties that consist of the applicant's proposed service area are presented in the table below:

Benton	Carroll	Chester	Crockett
Decatur	Dyer	Fayette	Gibson
Hardeman	Hardin	Haywood	Henderson
Henry	Houston	Lake	Lauderdale
McNairy	Madison	Obion	Perry
Shelby	Stewart	Tipton	Wayne
Weakley			

Service Area Historical Utilization

The applicant identified 61 existing home health agencies that reported utilization in at least one of the 25 service area counties. The applicant reported that 41,001 patients were served in 2011 increasing 1.9% to 41,778 patients in 2013.

Note to Agency members: The Joint Annual Report does not capture utilization data specific to home infusion patients. There is not a known public database available that reports this type of data.

When the Coram Alternative Site Services application for home infusion nursing for Middle Tennessee was reviewed in 2012, HSDA staff contacted the Tennessee

Association of Home Care (TAHC) regarding home health providers and the Tennessee Hospital Association (THA) regarding hospital-based home care providers.

TAHC indicated the following:

- TAHC membership applications on file indicate that 224 home health offices (parents and branches) offer infusion therapy services.
- Standard home health policy is that first dose should be completed in the hospital setting
- The majority of home health agencies partner with an infusion company for administration of the second dose in the home.
- The home health nurse continues to support the patient's needs with observations and reports to the physician. It is unrealistic to think that a home health provider could limit their care to only infusion therapy. Infusion may be the primary need but these are typically patients with multiple chronic illnesses and co-morbidities who need a holistic, multi-disciplinary approach to their health care
- The barriers to home infusion therapy are generally noted as staffing and adequate payment. This is a growing issue for all homecare providers as both governmental and commercial payors continue to look to provider payments to cut costs.
- Homebound status is only a Medicare issue. An infusion company would be held to the same standard if it were a Medicare-certified home health agency.

THA's response included that a "typical" home care provider does not provide infusion administration for:

- Patients requiring 6 hour therapies
- Medicare patients who are not homebound. This applies only to Medicare. Many non-Medicare patients who are not homebound are served
- Patients requiring first dose administration
- Patients requiring three doses daily

THA does go on to state that member home health agencies see patients in every county in the state and that there are pediatric programs often affiliated with pediatric hospitals such as Vanderbilt, Methodist LeBonheur, and East Tennessee Children's Hospital.

HSDA staff received confirmation in an email from a representative of TAHC that the TAHC information provided in 2012 is still accurate in 2014.

Projected Utilization (Applicant)

• 207 patients are projected in Year 1 and 228 patients in Year 2 representing 1,775 and 1,952 skilled nursing visits, respectively.

Project Cost

Major costs of the \$98,000 total estimated project cost are:

- Legal, Administrative, Consultants Fee- \$88,000 or 90% of total cost
- Prorated Lease- \$7,000 or 7% of total cost

For other details on Project Cost, see the revised Project Cost Chart on page 74R of the application.

Historical Data Chart

- Since this is a new proposed home health provider, a historical data chart was not available.
- However, the applicant provided a historical data chart for their existing pharmacy operation in Memphis, which reported a positive net operating income of \$580,471 in 2011 and \$246,431 in 2012; and \$119,353 in 2013.

Projected Data Chart

The Projected Data Chart for Coram Alternate Site Services reflects \$265,543.00 in total gross revenue on 1,775 patient visits/207 patients during the first year of operation and \$306,702.00 on 1,952 patient visits/228 patients in Year Two (approximately \$157.12 per visit or 1,345.18 per patient). The Projected Data Chart reflects the following:

- Net operating income is estimated at \$482 in Year One increasing to \$4,614 in Year Two.
- Projected NOI calculates to approximately 0.2% of gross revenues in Year 1 increasing to 1.5% in Year 2.
- Deductions from operating revenue for bad debt, charity care, and contractual adjustments are estimated at \$33,737 or approximately 11% of total gross revenue in Year Two.
- The applicant expects that 5% of its patients will be charity care totaling \$13,277 in Year One and \$15,335 in Year Two.

Charges

In Year One of the proposed project, the average charge per case is as follows:

- The proposed average gross charge is \$1,345.00/patient case
- The average deduction is \$148.00/patient case, producing an average net charge of \$1,197/patient case.
- The applicant's expected gross charge per visit in Year 2 is expected to be \$157. The applicant pointed out that the average gross charge per visits in area home health agencies ranged mainly from \$81 to \$120 with one agency reporting \$155. The applicant points out that if this range of

charges was projected to 2015, the applicant projected charge will fall within the range.

Medicare/TennCare Payor Mix

The applicant states that the licensed pharmacy participates in both Medicare and TennCare and serves medically indigent patients; however the proposed home health agency will not become Medicare/Medicaid certified because the agency will not be eligible for Medicare certification as a home health agency for the following reasons:

- Limited scope of service which means the agency would not be providing the full range of home health services as prescribed by the Medicare Conditions of Participation.
- The applicant's projected payor mix is 89% commercial insurance, 6% self-pay, and 5% charity care.

Financing

A May 31, 2014 letter from Coram Alternate Site Services, Inc. Senior Vice President confirms the availability of cash reserves to fund the \$98,000 proposed project.

CVS Caremark Corporation's unaudited financial statements for the period ending March 31, 2014 indicates \$2,776,000,000 in cash and cash equivalents, total current assets of \$24,460,000,000, total current liabilities of \$16,213,000,000 and a current ratio of 1.51:1.

Current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The applicant's direct patient care staffing for the home health agency is projected as 1.95 FTE Registered Nurses (RN) in Year One increasing to 2.15 RN FTEs in Year 2

Licensure/Accreditation

If approved, Coram Alternative Site Services, Inc. will be licensed by the Tennessee Department of Health. The applicant has provided information regarding the licensing and accreditation inspection surveys for Coram Alternative Site Services, Inc. home health services currently located in Nashville, TN. A letter dated February 4, 2013 from the Tennessee Department of Health, Office of Health Licensure and Regulation, states no deficiencies were found as a result of a survey completed on January 30, 2013.

The applicant's pharmacy operation is currently accredited by The Joint Commission.

Corporate documentation, real estate lease, and detailed demographic information are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in **two** years.

Note to Agency members: Should the Agency choose to approve this application, Staff recommends the Agency limit any future expansion of services by requiring a new application to expand services beyond infusion and infusion-related services rather than a modification request through the General Counsel's Report. This could be accomplished with the following condition:

Home Health Agency services are limited to infusion-related services. The expansion of services beyond the home infusion services described in the application will require the filing of a new certificate of need application

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied applications, or outstanding Certificates of Need for this applicant.

Pending Applications

Coram Alternative Site Services, Inc. d/b/a Coram Specialty Infusion Services, CN1406-017, has a pending application scheduled to be heard at the September 24, 2014 Agency meeting. The application is for the establishment of a home care organization to provide the following specialized home health services related to home infusion: administer home infusion products and related infusion nursing services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports. The proposed service area includes the following Tennessee counties: Anderson, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Fentress, Grainger, Greene, Hamblen, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Meigs, Monroe, Moore, Morgan, Pickett, Polk, Roane, Scott, Sevier, Sullivan, Unicoi, Union, Van Buren, and Washington, from its licensed home infusion pharmacy which will be located at 10932 Murdock Drive, Suite 101A, Knoxville (Knox County), TN 37932. The estimated project cost is \$95,200.00.

<u>CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA</u> FACILITIES:

There are no other pending applications for other health care organizations in the service area proposing this type of service.

Letters of Intent

Implanted Pump Management filed a letter of intent on July 3, 2014 for the establishment of a home health agency to service intrathecal pump services to patients across all 95 counties in the State of Tennessee. The estimated project cost is \$275,000.

Denied Applications:

Love Ones, CN1309-033D was denied at the February 26, 2014 Agency meeting for the establishment of a home health agency and initiation of home health services in Shelby, Fayette, and Tipton Counties. The parent office was to be located at 2502 Mount Moriah, Suite A-148, Memphis (Shelby County), TN 38116. The estimated project cost was \$177,800.00. Reasons for Denial: 1) Need-There has not been a supported need in this particular area as there are existing providers that have testified that they can accommodate a greater need than the actual patient census that they have proposed in the first two years of their business plan; Economic Feasibility-The project is not financially feasible considering the small number of patients, and they have underestimated the costs of what it is going to take to run a Medicare-certified agency.

Outstanding Certificates of Need:

Hemophilia Preferred Care of Memphis, CN1202-002, has an outstanding certificate of need that will expire on August 1, 2015. The CON was approved at the June 27, 2012 agency meeting for the establishment of a home health agency and the initiation of home health services limited to patients suffering from hemophilia or similar blood disorders who are patients of the pharmacy operated by Hemophilia Preferred Care of Memphis. The estimated project cost is \$43,000. Project Status: The applicant requested and received approval at the June 25, 2014 Agency meeting for a one year extension from August 1, 2014 to August 1, 2015.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

MAF 09/12/2014

LETTER OF INTENT



State of Tennessee **Health Services and Development Agency**

Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be possible of general circulation in see a for one day.	oublished in the(ATTACHMENT A Name of Newspaper) Tennessee, on or b	which is a newspape pefore June 3,4,5,20,1 (Month/day) (Year	
This is to provide official notice accordance with T.C.A. § 68-11-that: Coram Alternate Site Services,	1601 et seq., and the I	Rules of the Health	Services and Development Age	ency,
(Name of Applicant) CVS Caremark Corporowned by:	ration W	(F	usion Services Home healt acility Type-Existing) pe of for profit	<u>h</u> agency
and to be managed by:self-mana for [PROJECT DESCRIPTION BEGINS HER	ged		plication for a Certificate of Need	t
The anticipated date of filing the a	application is: June 6	. 20	14	
The contact person for this project	ctis_ Alix Coulter C		Attorney	
	•		(Title) C 333 Commerce Street, Suit Address)	ce 1500
Nashville (City) Ay at Company (Signature)	TN (State)	37201 (Zip Code)	(Area Code / Phone Number) alix.cross@h3gm.com (E-mail Address)	
The Letter of Intent must be filed in last day for filing is a Saturday, S this form at the following address:	unday or State Holiday	between the first and the first and the first and the first and the first are the first and the first and the first and the first and the first are the firs	and the tenth day of the month. It on the preceding business day.	the File

Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

HF51 (Revised 01/09/2013 – all forms prior to this date are obsolete)

ATTACHMENT A 18

Nowananar of Canaral Circulation	Date of
Newspaper of General Circulation	Publication
Brownsville States-Graphic	5th
Buffalo River Review	4th
Carroll County News - Leader	4th
Chester County Independent	5th
Crockett County Times	4th
Dresden Enterprise	4th
Dyersburg State Gazette	5th
Humboldt Chronicle	4th
Lake County Banner Inc.	4th
The Camden Chronicle	5th
The Commercial Appeal	4th
The Courier	5th
The Independent Appeal	4th
The Jackson Sun	5th
The Lauderdale County Enterprise	5th
The Leader	5th
The Lexington Progress	4th
The News Leader	4th
The Paris Post-Intelligencer	4th
The Stewart-Houston Times	3rd
The Union City Daily Messenger	4th
Wayne County News	4th

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County
Benton
Carroll
Chester
Crockett
Decatur
Dyer
Fayette
Gibson
Hardeman
Hardin
Haywood
Henderson
Henry
Houston
Lake
Lauderdale
Madison
McNairy
Obion
Perry
Shelby
Stewart
Tipton
Wayne
Weakley

ATTACHMENT C

To provide and administer home infusion products and related infusion nursing services ancillary to its pharmacy services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports within the following Tennessee counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, Madison, McNairy, Obion, Perry, Shelby, Stewart, Tipton, Wayne, and Weakley, from its current licensed home infusion pharmacy located at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee 38134 with an estimated project cost to not exceed \$98,000. Coram Alternate Site Services, Inc. is currently licensed in the following counties: Bedford, Bledsoe, Cannon, Cheatham, Clay, Coffee, Cumberland, Davidson, DeKalb, Dickson, Franklin, Giles, Grundy, Hamilton, Hickman, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Marion, Marshall, Maury, Montgomery, Overton, Putnam, Rhea, Robertson, Rutherford, Sequatchie, Smith, Sumner, Trousdale, Warren, White, Williamson, and Wilson.



State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

PUBLICATION OF INTENT

The following shall be published in the "Legal Notices" section of the newspaper in a space no smaller than two (2) columns by two (2) inches.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested partie accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agenta:							
), Inc. d/b/a Coram CVS/ specialt	y Infusion Services	зу				
(Name of Applicant)		(Facility Type-Existing) with an ownership type of for profit					
owned by:cvs caremark co	orporation						
and to be managed by: _	self-managed	intends to file ar	n application for a (Certificate of Need			
for [PROJECT DESCRIPTION BE	GINS HERE]: see attached						
The anticipated date of fili	ng the application is:	une 6	, 20				
The contact person for th	s project is	080	Atto	ney			
•		tact Name)		(Title)			
who may be reached at:	Harwell Howard Hyne Gabbert & M	anner, PC	333 Commerce Stre	et, Suite 1500			
in a many are readined and	(Company Name)		(Addres	ss)			
Nashville	'LN	37201	615	/ 256-0500			

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

HF50 (Revised 01/09/2013 - all forms prior to this date are obsolete)

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-3601 et seq., and the Rules of the Health Services and Development Agency, that Coram Alternate Site Services, Inc. d/b/a Coram CVS/ specialty Infusion Services, owned by CVS Caremark Corporation, with an ownership type of for profit corporation to be self-managed, intends to file an application for a Certificate of Need for the establishment of a limited service home health agency only to provide and administer home infusion products and related infusion nursing services ancillary to its pharmacy services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports within the following Tennessee counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, Madison, McNairy, Obion, Perry, Shelby, Stewart, Tipton, Wayne, and Weakley, from its current licensed home infusion pharmacy located at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee 38134 with an estimated project cost to not exceed \$98,000. Coram Alternate Site Services, Inc. is currently licensed in the following counties: Bedford, Bledsoe, Cannon, Cheatham, Clay, Coffee, Cumberland, Davidson, DeKalb, Dickson, Franklin, Giles, Grundy, Hamilton, Hickman, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Marion, Marshall, Maury, Montgomery, Overton, Putnam, Rhea, Robertson, Rutherford, Sequatchie, Smith, Sumner, Trousdale, Warren, White, Williamson, and Wilson.

The anticipated filing date of the application is June 6, 2014.

The contact person for this project is Alix Coulter Cross, Attorney, who may be reached at Harwell Howard Hyne Gabbert & Manner PC, 333 Commerce Street, Ste. 1500, Nashville, TN 37201, 615/256-0500.

Upon written request by interested parties a local fact-finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, Tennessee 37243

The published letter of intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

COPY -Application Coram CVS Speciality Infusion Services,M

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Thank you for your payment. Have a nice day!

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CORAM ALTERNATE SITE SERVICES, INC. CERTIFICATE OF NEED APPLICATION TO ESTABLISH A LIMITED SERVICE HOME HEALTH AGENCY WEST TENNESSEE

JUNE 2014

SECTION A APPLICANT PROFILE

CORAM ALTERNATE SITE SERVICES, INC.

1.	Name of Facility, Agency, or Institution					
	Coram Alternate Site Services, Inc. d/b/a Coram CVS/specialty Infusion Services					
	Name					
	1680 Century Center Parkway, Suite 12 Street or Route	Shelby County				
	Memphis TN	38134				
	City State	Zip Code				
2.	Contact Person Available for Responses to Questions					
	Alix Coulter Cross	Attorney				
	Name	Title				
	Harwell, Howard, Hyne, Gabbert and Manner Company Name	alix.cross@h3gm.com Email address				
	333 Commerce Street, Suite 1500 Nashville Street or Route City	TN 37201 State Zip Code				
	Counsel 615-251-1047 Association with Owner Phone Number	615-251-1059 Fax Number				
3,	Owner of the Facility, Agency or Institution					
	Coram Specialty Infusion Services, Inc.	303-292-4973				
	Name	Phone Number				
	555 17th Street, Suite 1500 Street or Route	Denver County				
	Denver	80202				
	City State	Zip Code				
	Type of Ownership of Control (Check One)					
	B. Partnership C. Limited Partnership D. Corporation (For Profit) G. Political S H. Joint Ven	ent (State of TN or Subdivision) ture ability Company				
	E. Corporation (Not-for-Profit) Other (Sp					

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5.	Not Applicable Not Applicable Name Street or Route City State Zip Code					
	PUT ALL ATTACHMENTS AT THE REFERENCE THE APPLICABLE IT	EM NUMBER	ON ALL ATTACHMENTS.	DER AND		
6.	A. Ownership B. Option to Purchase C. Lease of 5 Years PUT ALL ATTACHMENTS AT THREFERENCE THE APPLICABLE IT	D. E.	Option to Lease Other (Specify) THE APPLICATION IN OR	DER AND		
7.	 Type of Institution (Check as approximate) A. Hospital (Specify) B. Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty C. ASTC, Single Specialty D. Home Health Agency E. Hospice F. Mental Health Hospital G. Mental Health Residential Treatment Facility H. Mental Retardation Institutional Habilitation Facility (ICF/MR) 	J. J. K. L. M. N.	Nursing Home Outpatient Diagnostic Cente Recuperation Center Rehabilitation Facility Residential Hospice Non-Residential Methadone Facility Birthing Center Other Outpatient Facility (Specify) Other (Specify)			
8.	Purpose of Review (Check) as apple A. New Institution B. Replacement/Existing Facility C. Modification/Existing Facility D. Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify) Home Health-Limited Svc E. Discontinuance of OB Services F. Acquisition of Equipment	ropriatemor	change in Bed Complement [Please note the type of change by underlining the appropriate response: Increase, Decrease Designation, Distribution, Conversion, Relocation] Change of Location Other (Specify)	ge		

9.	Bed Complement Data Please indicate current and proposed distribution and certification of facility beds.							
				Current L Licensed		Staffed Beds	Beds Proposed	TOTAL Beds at Completion
	A.	Medical		N. Gerigie	والمحارا		AGE AND	Market
	B.	Surgical		TO A SE				12001000
	C.	Long-Term Care Hospital						an alien
	D.	Obstetrical		10,00000	CS (WHO		1500 P000	The state of the s
	E.	ICU/CCU		10 12/10	Beautie	DEL SOL	Note: In	(31.84)
	F.	Neonatal		SU FEMALES	-1000			12000550
	G.	Pediatric		1000000	Miles and	ISTANCE IN	SECTION.	((4))=11
	Н.	Adult Psychiatric			COLUMN TO		THE WAY	(894500)
	1.	Geriatric Psychiatric		(D ZP)	118,507 11	375.043	/Essate	0.5773,4333
	J.	Child/Adolescent Psychiatric		£1132/1	MEYEN N	255	102 785	action to the
	K.	Rehabilitation					27.4	1975-401
	L.	Nursing Facility (non-Medicaid	Certified)	EEE	OLEVIET.			101
	M.	Nursing Facility Level 1 (Medic	caid only)					10000
	N.	Nursing Facility Level 2 (Medic	care only)					
	Ο.	Nursing Facility Level 2 (dually certified Medicaid/Medicard	e)	10000				
	P.	ICF/MR				1-01-21	712650	272961
	Q.	Adult Chemical Dependency		epilenesi			-440811	SU177
	R.	Child and Adolescent Chemic Dependency	al				1 A 1	(652Au
	S.	Swing Beds		F-32-30	21707	1997	11.52	1.5792
	T.	Mental Health Residential Tre	atment		HX3125		802000	
	U.	Residential Hospice			PESTS I			
		TOTAL		0	0	0	0	0
		*CON-Beds approved but not yet	in service	()	0	() () () () () () () () () () () () () () (31	X ===== X
10.	N	ledicare Provider Number	0976970045	10 to 15				
		Certification Type	_Pharmacy/DME	EPOS				
11.	Λ	ledicaid Provider Number	1629184957 and	d 1452078	The time is	NY DV	BIEST VERY	
		Certification Type Pharmacy and DME (instate); additional numbers for Mississippi						
12.	lí	If this is a new facility, will certification be sought for Medicare and/or Medicaid?						
13.	(/ ti	Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area. Will this project involve the treatment of TennCare participants? YES If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.						
	L	Discuss any out-of-network relationships in place with MCOs/BHOs in the area.						

SECTION A: APPLICANT PROFILE, ADDITIONAL RESPONSES

For Section A, Item 3, Attach a copy of the partnership agreement, or corporate charter and certificate of corporate existence, if applicable, from the Tennessee Secretary of State.

The Applicant is a Delaware Corporation which is a wholly owned subsidiary of Coram Specialty Infusion Services, Inc. These entities ultimate parent is CVS Caremark Corporation. The Applicant's confirmation of corporate existence from the Tennessee Secretary of State is included in Attachment, Section A, Item 3.1. Its By Laws are included in Attachment, Section A, Item 3.2.

For Section A, Item 4, describe the existing or proposed ownership structure of the applicant, including an ownership structure organizational chart. Explain the corporate structure and the manner in which all entities of the ownership structure relate to the applicant. As applicable, identify the members of the ownership entity and each member's percentage of ownership, for those members with 5% or more ownership interest. In addition, please document the financial interest of the applicant, and the applicant's parent company/owner in any other health care institution as defined in Tennessee Code Annotated, §68-11-1602 in Tennessee. At a minimum, please provide the name, address, current status of licensure/certification, and percentage of ownership for each health care institution identified.

A description of the Applicant and its Organizational Chart are included in Attachment, Section A, Item 4.1. The Applicant's ultimate parent's most recently filed 10-K (annual report) with the Securities and Exchange Commission is included in Attachment, Section A, Item 4.2. The Applicant owns a limited service home health agency in Middle Tennessee serving 38 Tennessee Counties. The license for this Agency is included in Attachment, Section A, Item 4.3. This is the only entity which the Applicant has a financial interest as defined by TCA §68-11-1602(7) in Tennessee.

For Section A, Item 5, for new facilities or existing facilities without a current management agreement, attach a copy of a draft management agreement that at least includes the anticipated scope of management services to be provided, the anticipated term of the agreement, and the anticipated management fee payment methodology and schedule. For facilities with existing management agreements, attach a copy of the fully executed final contract. Please describe the management entity's experience in providing management services for the type of the facility, which is the same or similar to the applicant facility. Please describe the ownership structure of the management entity.

Coram Alternate Site Services, Inc. is a self managed operation with its employed leadership operating the entity on a day to day basis, reporting to regional directors who ultimately report to the holding company's executive leadership and board. This question is not applicable to the Applicant.

For Section A, Item 6, for applicants or applicant's parent company/owner that currently own the building/land for the project location; attach a copy of the title/deed. For applicants or applicant's parent company/owner that currently lease the building/land for the project location, attach a copy of the fully executed lease agreement. For projects where the location of the project has not been secured, attach a fully executed document including Option to Purchase Agreement, Option to Lease Agreement, or other appropriate documentation. Option to Purchase Agreements must include anticipated purchase price. Lease/Option to Lease Agreements must include the actual/anticipated term of the agreement and actual/anticipated lease expense. The legal interests described herein must be valid on the date of the Agency's consideration of the certificate of need application.

The Applicant and its predecessor entities have occupied its existing 6,766 square feet of leased since 1992, more than 20 years, under a Lease Agreement with the landlord (and its predecessor entities). The current governing amendment to the Lease Agreement is the Fourth Amendment which is a five year term commencing June 2010 and terminating June 2015. The existing leased space is sufficiently sized to add the restricted home health services to its business lines and effectively operate the licensed pharmacy and home health services with common leadership and facilities. A copy of the Lease Agreement with all Four Amendments is included in Attachment, Section A, Item 6.1.

For Section A, Item 13, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract with.

Coram Alternate Site Services, Inc., and its affiliate Coram Specialty Infusion Services, Inc. have historically and will continue to contract with Tennessee Managed Care Organizations.

There are four TennCare MCOs within the state. TennCare Select and United Healthcare serve all three regions. BlueCare serves the East and West region; and Amerigroup serves the Middle Tennessee region. Currently the Applicant contracts with BlueCare/TennCare Select in Tennessee and contracts with Amerigroup on a national level. The existing contract covers the Applicant's infusion services. The Applicant does not intend to certify its limited service home health agency for Medicare and Medicaid (TennCare) services as it will not be a full service agency and therefore does not meet the Conditions of Participation for such certification.

In addition to TennCare MCOs, the Applicant contracts with a host of commercial managed care organizations that serve the region for its infusion products. These entities include, but are not limited to, the following: Aetna, Blue Cross Blue Shield of Tennessee, Carecentrix, Cigna, Corizon, Coventry, Cover Tennessee, GEHA, Multiplan, HealthSprings of Tennessee, Magellan TennCare, Prime Healthcare, Medicare, St Jude and TriCare. Nursing services to administer the infusion products will be added to these contracts. As necessary, additional MCOs will be added to the Applicant's contractual arrangements as its services expand.

SECTION B PROJECT DESCRIPTION

CORAM ALTERNATE SITE SERVICES. INC.

SECTION B: PROJECT DESCRIPTION

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

The applicant is Coram Alternate Site Services, Inc., a Delaware corporation, which operates a licensed pharmacy at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee 38134 ("Coram" or "Applicant"). Its d/b/a is Coram CVS/specialty Infusion Services. It is both licensed by the State and accredited by The Joint Commission. These documents are included in Attachment, Section B, Project Description, Item I. This Coram branch provides home infusion products to residents throughout West Tennessee spanning from the Tennessee-Arkansas/Missouri state line on the west, Shelby County and Memphis to the southwest, the western Tennessee-Mississippi state line on the south, the western Tennessee-Kentucky state line on the north and the communities of Dover, Erin, Camden, Linden, Waynesboro along the east of this defined service area. In addition to serving Tennessee residents, this Coram branch also serves residents of the neighboring states of Arkansas and Mississippi. Through its Coram affiliate, Coram provides limited nursing services in Mississippi enabling the continuum for those West Tennessee branch pharmacy patients who reside in Mississippi.

While Coram serves this tri-state region, the focus of this CON application is to become a licensed limited service home health agency to meet the needs of Tennesseans. This 25-county West Tennessee proposed service area represents 86 percent of the Tennessee related home infusion services provided by Coram from its Memphis Branch. The balance of its Tennessee infusion therapy product patients is transferred to the other Tennessee branches; they will not be served by the Memphis branch home health agency under its proposed licensure. Relative to out of state patients, Coram's Memphis branch in aggregate does have meaningful counts of patients with 79 percent of its total patient complement living in Tennessee and 21 percent residing out of state.

The Applicant is a wholly owned subsidiary of Coram Specialty Infusion Services, Inc. which has as its ultimate parent CVS Caremark Corporation, also a Delaware corporation. Coram's ultimate parent is controlled by its executive officers and board of directors. CVS is a publicly traded stock corporation on the New York Stock Exchange (NYSE: CVS).

Through the submission of this CON application, the Applicant is seeking to establish a limited service home health agency. Specifically, with its approved home health agency license, the Applicant will only provide and administer home infusion products and related infusion nursing services. As part of its administration of home infusion therapies the Applicant intends to (a) take and record vital signs of the patients; (b) draw blood and other fluids for labs; (c) treat any issues associated with the access site or port; (d) change dressings associated with access points; (e) administer the therapy or

blood products; (f) line maintenance; and (g) infusion equipment repair and replacement.

These services will be provided by a registered nurse who is appropriately credentialed and is certified with a CRNI designation (certified registered nurse infusion). These services and credentials are a unique service and not typical of the average Medicare certified home health agency available to West Tennesseans.

For patients in need of home health services other than those associated with the Applicant's delivery and administration of home infusion products, the Applicant will make reasonable efforts to communicate that need with the patient's treating physician who can order such services through another licensed home health agency ("HHA"). The Applicant will not provide the service when another full service HHA stands ready willing and able to serve the patient. In other words, "If they can do it all, we will give it to them."

The administrator of the Coram home health agency will be the existing Regional Nurse Manager of the Memphis Branch, Ms. Nicole Kirby, as this service will be seamlessly added to the existing infrastructure of the Memphis Branch. Ms. Kirby meets the home health administrator criteria as prescribed by Rules of Tennessee Department of Health, Board of Licensing, Chapter 1200-08-26.

The defined service area of the proposed home health agency is 25 counties throughout West Tennessee which is the geographic area in which most of the Coram Memphis branch Tennessee infusion therapy product patients reside. Evaluation of these patients' records for the past three years identified the infusion product profile, age profile, payor profile, and referral sources including place of hospitalization of these patients. Documentation by Coram relative to the hardships for these patients to receive infusion nursing services in the home is also provided through anecdotes, patient stories and concurrent documentation by Coram staff. The delay in treatment and hardships identified contribute to extended lengths of stay in hospital, more costly hospital stays, increased costs to the healthcare system overall, and economic hardships on the patients and families.

The types of home health patients to be served by Coram will be restricted to infusion therapy patients. Types of infusion products to be administered include: antibiotics; total parenteral nutrition (TPN); hydration; cardiac products (such as inotropic therapies); intravenous immunoglobulin (IVIG) and other similar specialty drugs; pain management; antiemetic; and steroids. The types of patients served by Coram who have demonstrated needs for infusion nursing services in the home which are otherwise unavailable from other home health agencies include the following:

Specialty Patients Requiring IVIG and Alpha 1 Therapies: IVIG, intravenous immunoglobulin, is given as a plasma protein replacement therapy for immune deficient patients who have decreased or abolished antibody production capabilities. Alpha-1 antitrypsin infusion therapy is given to treat the genetic

- disorder alpha 1-antitrypsin deficiency that causes defective production of the alpha 1-antitrypsin (A1AT) leading to decreased A1AT in the blood and lungs.
- > First Dose Administration: First Dose Administration is the first time a prescribed infusion therapy is provided to the patient.
- ➤ Low Intervention Patients: A Low Intervention Patient is a patient who is not homebound and does not require significant nursing intervention. Rather s/he comprises the group of patients who are taught to self administer thereby limiting the number of home skilled nursing visits.
- ➤ Three Dose Schedule Patients: Three Dose Schedule Patients are infusion therapy patients whose therapy is administered three times throughout the day (i.e., 6 am, 2 pm and 10 pm).
- ➤ Rural and Pediatric Patients: Rural Patients are infusion therapy patients who reside well outside the major cities in West Tennessee such as Memphis, Jackson and Covington where major medical centers and infusion providers are prevalent. Pediatric Patients are children who require infusion therapy products and services.

The Applicant is differentiated from other area home health agencies because it not only serves the above unique types of patients but also its nursing staff is specially trained in the art and skill of providing infusion therapies, most are certified, have over 1,600 hours of clinical infusion therapy experience, and have developed training and skills necessary to identify, collaborate and treat infusion therapy related effects, as well as communicate to patients on proper care of catheter sites, sterile treatment and monitoring of equipment and supplies.

Provided the patient qualifies for home health services (e.g., home bound), and after the first dose, and provided that the therapy is not of repeat or long duration, existing home health agencies such as Home Health Care of West Tennessee, Methodist, Homechoice and Baptist, have on occasion provided care to the Applicant's patients. In general, though, these arrangements do not work because: (a) many of these patients are not truly home bound so they do not qualify for reimbursement, and thus the HHAs do not want these patients; (b) because many of these therapies are of a long duration (3+ hours) it is not economically feasible for a full service agency to tie up an RN for that length of time; (c) because none of the full service agencies will do first dose patients; and (d) because none will any infuse blood or blood products in the home.

As discussed in this application, the Applicant will employ one (1) full time infusion nurse centrally located in Memphis, and will add per diem, or per visit, infusion nurses throughout the service area as needed to respond expeditiously to requests for service. Operationally, on occasion if the patient is local, the infusion nurse will take the infusion product from the compounding pharmacy to the patient's home for administration. More often, the infusion product will be compounded at the Applicant's Century Center Parkway facility and taken by secure courier to the patient's home where it is met by the infusion nurse for administration.

The Applicant's encounter with a patient begins when the patient's attending physician orders an infusion product or service and a referral is made to the Applicant (either by

the physician or discharge planners at area medical centers). The Applicant verifies insurance, the physician order, and the patient's demographic information and transmits that data to the pharmacy which compound's the patient's drug therapy. Three groups within the Applicant then coordinate the patient's care: the pharmacy with respect to the drug mix, the courier service for secure and timely delivery, and nursing for education and administration. The Applicant has implemented an electronic medical record system that securely communicates with the home office regarding nursing encounter notes for services rendered in the home and summaries of care are shared with the patient's physician.

The Applicant employs a Regional Nurse Manager who will be the supervisor for all the nursing functions associated with the Applicant, who will be available at all times during operating hours and shall participate in all activities relevant to the professional home health services provided, including the development of qualifications and assignment of personnel. In addition, the Applicant agency shall have a committee, consisting of the Regional Nurse Manager / agency executive director and the regional president who shall review at least annually past and present HHA services to determine the appropriateness and effectiveness of the care provided.

The uniqueness of Coram's patient population drives the need for Coram to be licensed as a home health agency. Approval of Coram's restricted home health license will enable a specific subset of the population to receive a higher standard of care in a lower cost environment, thereby contributing to the orderly development of healthcare while meeting a distinct patient and community need. The underlying bases and discussions relative to the lack of access and availability of skilled infusion nursing services for this patient population is provided in response to Section C, Need: Home Health Services, Question 1 along with supporting discussions in response to the other Home Health Services, Guidelines for Growth and General Criteria related to Need.

There is no construction associated with this project and there is no major medical equipment involved with this project. Its costs are limited to the administrative, legal and consulting costs associated with obtaining certificate of need approval and costs associated with licensure. The total cost for the project is \$98,000. Its funding can be assured based on the financial statements of the ultimate parent as provided in Attachment, Section A, Item 4.2, the letter of funding commitment included with this CON application as Attachment, Section C, Economic Feasibility, Item 2.1 and the local branch's financial statements provided as Attachment, Section A, Item 4.4. Demonstration of Economic Feasibility and how this project makes a Contribution to the Orderly Development of Healthcare is presented in response to those sections in this application.

Operationally, the Applicant will operate the home health service as part of its existing Memphis Branch operations. Adding the nursing service to its existing product line will enhance the operation while providing its patients with a service that is historically difficult to obtain resulting in prolonged hospital stays, ineffective or inefficient care and compromised quality of care. The financial projections which are a part of this Application demonstrate that this service is restricted in its scope, is financially feasible and generates a positive net income from operations.

- II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.
 - A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project. If the project involves none of the above, describe the development of the proposal.

Coram Alternate Site Services, Inc. occupies 6,766 square foot structure (Suite 12) at 1680 Century Center Parkway, Memphis, Tennessee 38134. This existing space houses its licensed pharmacy services and includes the pharmacy, distribution warehouse and administrative offices and support space. The addition of the restricted home health services will be under the existing leadership and operate from the existing leased space. Accordingly, there is no construction, renovation or modification required to implement this proposed project.

The square footage chart for the currently leased space which will house the home health service is included as Attachment, Section B, Project Description, Item II (A). Square footage was estimated from the existing floor plan as the space is currently occupied by the Applicant. There are no costs to establish the program as the home health services will be supported from the existing administrative spaces while the actual service will be provided in the client (patient) home.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

This question addresses a change in bed capacity. This CON application is for a limited service home health agency. Therefore this question is not applicable to the project proposed herein.

- C. As the applicant, describe your need to provide the following health care services (if applicable to this application):
 - 1. Adult Psychiatric Services
 - 2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
 - 3. Birthing Center
 - 4. Burn Units
 - 5. Cardiac Catheterization Services
 - 6. Child and Adolescent Psychiatric Services
 - 7. Extracorporeal Lithotripsy
 - 8. Home Health Services
 - 9. Hospice Services
 - 10. Residential Hospice
 - 11. ICF/MR Services
 - 12. Long-term Care Services
 - 13. Magnetic Resonance Imaging (MRI)
 - 14. Mental Health Residential Treatment
 - 15. Neonatal Intensive Care Unit
 - 16. Non-Residential Methadone Treatment Centers
 - 17. Open Heart Surgery
 - 18. Positron Emission Tomography
 - 19. Radiation Therapy/Linear Accelerator
 - 20. Rehabilitation Services
 - 21. Swing Beds

The Applicant has defined an unmet community need to provide home health services limited to infusion nursing and related services. The need for this service results from a lack of available or accessible home infusion nursing capability throughout West Tennessee. As a licensed pharmacy providing infusion therapy products to patients in their homes, Coram is intimately familiar with the patients throughout the region, and the hardships encountered by hospitals, physicians and patients/families in effecting a timely discharge from the hospital when hospitalization is no longer required, but the patient and family have not initiated their first infusion dose nor are they knowledgeable about the process, the infusion equipment, and the specific regimen which must be followed. Furthermore, as the pharmacy providing the infusion product to the patient, Coram's staff regularly meets with the patients and understands their skilled nursing needs, but is unable to assist in that regard as it does not have a home health license. The types of infusion patients which have compromised access and how Coram will meet their needs are discussed in response to Sections B and Section C on the following pages.

As noted in this application, this patient population's needs are not being met by the existing HHA providers, primarily because of reimbursement and conditions of participation issues. Existing resources cannot get reimbursed for patients who are not home bound; they cannot get adequately reimbursed for an infusion therapy that lasts several hours; and they only get reimbursed for one visit, even though three therapy regimens require 3 visits in the same day. Furthermore, the existing agencies will not treat patients on their first dose, and will not administer blood or blood products in the home.

By granting the Applicant's limited service HHA CON request, these patients can remain in their home, thereby avoiding the time and inconvenience of traveling to an outpatient hospital clinic, as well as avoiding exposure of their immune suppressed bodies to nosocomial infections. Finally, the care rendered by the Applicant's certified infusion nurses is vastly superior to that of the RN untrained in spotting infusion complications, educating patients on sterile site and site maintenance.

With the approval of this CON application, Coram will be able to serve a patient population in need in a more appropriate, cost effective and accessible manner, in their own home, thereby meeting a defined need while contributing to the orderly development of healthcare.

D. Describe the need to change location or replace an existing facility.

This question addresses the need to change location or replace an existing facility. This CON application is for a limited service home health agency. Therefore this question is not applicable to the project proposed herein.

- E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:
 - 1. For fixed-site major medical equipment (not replacing existing equipment):
 - a. Describe the new equipment, including:
 - 1. Total cost; (As defined by Agency Rule).
 - 2. Expected useful life;
 - 3. List of clinical applications to be provided; and
 - 4. Documentation of FDA approval.
 - b. Provide current and proposed schedules of operations.
 - 2. For mobile major medical equipment:
 - a. List all sites that will be served;
 - b. Provide current and/or proposed schedule of operations;
 - c. Provide the lease or contract cost.
 - d. Provide the fair market value of the equipment; and
 - e. List the owner for the equipment.
 - 3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

This question addresses the acquisition of major medical equipment. This CON application is for a limited service home health agency. Therefore this question is not applicable to the project proposed herein.

- III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:
 - 1. Size of site (in acres);
 - 2. Location of structure on the site; and
 - 3. Location of the proposed construction.
 - 4. Names of streets, roads or highway that cross or border the site.

 Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

The home health service will be located at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee. This 6,766 square foot suite is subject to an ongoing lease agreement between Coram and its landlord. The restricted service home health will be operated from this existing leased space. No modification, construction or renovation is required; nor is the addition of any further people to the management team.

The Site Plan and location of the building on the site relative to the surrounding streets and neighborhoods is included as Attachment, Section B, Project Description, Item III (A).

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

Accessibility to Coram's location is not applicable as the home health services will not be provided at Coram's Memphis Branch. The purpose of this CON application is to obtain approval to provide these limited nursing services in the patient's home which will be in one of the 25 counties for which CON approval is being sought. The Coram nurse who will provide the service will reach the patient's home by private vehicle.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper. NOTE: <u>DO NOT SUBMIT BLUEPRINTS</u>. Simple line drawings should be submitted and need not be drawn to scale.

The Floor Plan of the leased building suite is included as Attachment, Section B, Project Description, Item IV. This suite is subject to an existing lease between the Applicant and landlord. It will not be modified within the context of this proposal as the home health service will operate from the administrative space within the leased space by the Branch's leadership.

- V. For a Home Health Agency or Hospice, identify:
 - 1. Existing service area by County;
 - 2. Proposed service area by County;
 - 3. A parent or primary service provider;
 - 4. Existing branches; and
 - 5. Proposed branches.

This CON application is for a limited service home health agency whereby its license will be restricted to provide only infusion nursing and related skilled services. The Applicant intends to provide the following skilled services in conjunction with its home infusion therapy products: (a) take and record vital signs of the patients; (b) draw blood and other fluids for labs; (c) treat any issues associated with the access site or port; (d) change dressings associated with access points; (e) administer the therapy or blood products; (f) line maintenance; and (g) infusion equipment repair and replacement.

The Applicant has three pharmacy branches in the state, serving east (from Knoxville), middle (from Nashville) and west (from Memphis). Additionally, the Applicant established its first Tennessee limited service home health agency in May 2013. The CON approved and subsequently licensed program is based out of the Applicant's Nashville office at 2970 Sidco Drive, Nashville, Tennessee. It is licensed to serve 38 counties within Middle Tennessee.

The purpose of this CON application is to obtain CON approval to serve the 25 counties in the western third of the State of Tennessee, which is defined as all counties west of the Middle Tennessee service area approved via CN #1205-020A. The specific West Tennessee counties for which CON approval is sought via this CON application are presented in the following chart:

Benton	Gibson	Houston	Perry
Carroll	Hardeman	Lake	Shelby
Chester	Hardin	Lauderdale	Stewart
Crockett	Haywood	Madison	Tipton
Decatur	Henderson	McNairy	Wayne
Dyer	Henry	Obion	Weakley
Fayette			

The geographic area represented by these counties spans from the Tennessee-Arkansas/Missouri state line on the west to the communities of Dover, Erin, Camden, Linden, Waynesboro along the east, Shelby County and Memphis to the southwest, the western Tennessee-Mississippi state line on the south, and the western Tennessee-Kentucky state line on the north.

A graphic depiction of this proposed West Tennessee Service Area and how it situates within the State and contiguous to the already licensed Middle Tennessee service area is presented below. The area represented in 'yellow' is the West Tennessee service area proposed via this CON application; the blue area are those counties which have been approved and licensed for a Coram limited service home health license via CN #1205-020A referenced above.



A full size map depicting the proposed West Tennessee counties relative to the State of Tennessee and the already licensed Coram Middle Tennessee service area (CN #1205-020A) is included in Attachment, Section B, Project Description, Item V.

SECTION C GENERAL CRITERIA FOR CERTIFICATE OF NEED

CORAM ALTERNATE SITE SERVICES, INC.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11 " white paper. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED:

NEED

- 1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.
 - 1. <u>Improve the Health of Tennessee</u>. Health in Tennessee will be improved through the approval of this project because current immune compromised individuals will not be required to leave their home and expose themselves to advantageous pathogens to receive their life-saving therapies. Patients will be trained in self care and administration in their own homes thereby enhancing the quality of their lives. Additionally, patients will be able to have their 'first dose' at home, not requiring an extended hospital stay, travel to an infusion center, or other factors negatively impacting the patient physically, emotionally or economically.
 - 2. <u>Reasonable Access to Care for Every Citizen</u>. By making these services more widely available in the home, access to even some of the most remote citizens is improved because they will no longer be required to travel to a major medical center for outpatient infusion therapy.
 - 3. <u>Health care resource development that encourages competitive markets, economic efficiencies and continued development of the state's healthcare system</u>. The proposed project makes these improvements in healthcare at minimal cost and disruption by narrowly focusing on a particular patient population whose needs are not being fully served, or who are being served but at great expense when in home care would be much safer and less costly.
 - 4. <u>Confidence in the quality of healthcare is continually monitored and standards are adhered to by providers</u>. The Applicant's nursing director will review a sufficient sample of patient charts for each caregiver to identify and eliminate poor quality of care, and to accentuate and reward outstanding quality of care and outcomes.
 - 5. <u>State support for development, recruitment and retention of a sufficient and quality healthcare workforce</u>. The Applicant intends to maintain one full time registered infusion nurse in Memphis and employ certified infusion nurses on a per diem or per visit basis thereby supporting a highly skilled and specialized nursing workforce throughout West Tennessee.
 - a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.

The criterion and standards in Certificate of Need Categories that are applicable to this project include: Home Health Services. Each of the Home Health Guidelines along with the associated responses is provided on the following pages.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED:

NEED: HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.

Home Health Services are regulated under Tennessee Chapter 1200-08-26, Board of Licensing. Tennessee Code Annotated (T.C.A.) § 68-11-201 defines a Home Care Organization as one that provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence. T.C.A. further defines home health services as a service provided an outpatient by an appropriately licensed health care professional or an appropriately qualified staff member of a licensed home care organization in accordance with orders recorded by a physician, and which includes one or more of the following:

- > Skilled nursing care including part time or intermittent supervision
- > Physical, occupational or speech therapy
- Medical social services
- Home health aide services
- Medical supplies and medical appliances

This CON application to become approved and licensed as a home health services agency is unique in that the Applicant is only seeking CON approval to enable it to provide one of the above services – skilled nursing care – and on a limited basis for a specific subset of patients in each county. Specifically, the skilled nursing care the Applicant is seeking licensure to provide is the administration of home infusion products and related infusion nursing services.

As part of its administration of home infusion therapies the Applicant intends to (a) take and record vital signs of the patients; (b) draw blood and other fluids for labs; (c) treat any issues associated with the access site or port; (d) change dressings associated with access points; (e) administer the therapy or blood products; (f) line maintenance; and (g) infusion equipment repair and replacement.

These services will be provided by a registered nurse who is appropriately credentialed and is certified with a CRNI designation (certified registered nurse infusion). These services and credentials are a unique service and not typical of the average Medicare certified home health agency available to West Tennesseans.

Need for this special service was developed by the Applicant based on its existing infusion therapy patient profiles including age, county of residence, infusion service requirement, payor, referral source, and identified hardship

experiences by patients, families and their referral sources (hospitals, physicians and others) to obtain infusion nursing service in the home on a timely basis. Depending on the urgency, day of week, and hour of the day, the Applicant makes commercially reasonable efforts to see patients within 2 to 3 hours of physician order which the Applicant believes to be a 'timely basis'. Unfortunately, the situation in West Tennessee is that these patients do not receive services on a timely basis, if the services become available at all. These healthcare delivery challenges are discussed further below in the Applicant's Service Area Study.

If a hospital inpatient prescribed infusion therapy services is unable to obtain home health assistance upon hospital discharge that individual remains in the hospital until s/he receives the first infusion and training sufficient that s/he could be discharged home to self-infuse thereafter. Subsequently, the Applicant would send the compounded infusion product from the Memphis pharmacy via secure medical courier. If the infusion therapy is inappropriate to administer in the home without nursing supervision, such as blood products or IVIG, the patient must travel to an outpatient clinic, such as an oncology clinic, physician practice, hospital or ambulatory infusion suite to obtain their medication. In addition, patients without nursing assistance who self-infuse in the home are ill equipped to handle even the most minor of complications, such as a blocked line, and must instead travel to the nearest hospital emergency room, sometimes by private transportation, but also by ambulance, to alleviate the problem. Similarly, patients who require a line change must also go to a hospital for such a procedure. All of these situations, and their attendant expenses, would be substantially eliminated by the Applicant implementing its limited service home health agency.

As an existing licensed pharmacy provider in Tennessee, the Applicant has a range of home infusion products it provides to its patients some of whom are homebound while others are not. Types of infusion products prescribed for its patients include, but are not limited to, the following:

- Antibiotics
- Total parenteral nutrition (TPN)
- > Hydration
- Cardiac products (such as inotropic therapies)
- > Intravenous immunoglobulin (IVIG) and other similar specialty drugs
- > Pain management
- > Antiemetic
- Steroids

During each of the past three years, the Applicant from its Memphis Branch has provided these types of infusion products to between 807 and 1,050 patients per year. Some of these patients received more than one infusion product (therapy). Because infusion therapy products are generally not one dose but can last over a period of time, shortest being days and longest being years, utilization is not only

measured by number of patients or number of therapies, but also by patient month, census and number of new patients by quarter. Patient months are the average number of months on infusion service for the total patient count. During the past three years, patient months have totaled between 1,500 and 1,900 months, or roughly two months on average per patient.

Following is the most recent 2013 activity, by quarter, for the Applicant's Memphis Branch:

Factor	Q1-2013	Q2-2013	Q3-2013	Q4-2013	CY 2013
Patients	205	207	203	192	807
New Patients	118	128	123	118	487
Therapies	240	238	231	209	918
Patients with Multiple Therapies	51	51	51	68	221
Average Therapies per Patient	1.17	1.15	1.14	1.09	1.14
Patient Months					1,532
Average Patient Age	48	50	54	48	50

On an ongoing basis, the Applicant has documented difficulties in meeting the infusion nursing needs of its infusion therapy patients. This skilled nursing access problem arises from several different associated factors, each of which is summarized in the following paragraphs substantiated by the Applicant's Service Area Study which follows.

- > Specialty Patients Requiring IVIG and Alpha 1 Therapies: These immunotherapy patients receive comparatively long infusions, lasting up to 6 hours for each therapy, generally only one time per month. Because of the duration of the infusion time and only once per month requirement, existing home health agencies do not provide this service. challenge with these patients is some receive blood based products or plasma derivatives which result in higher rates of patient reaction. Existing home health agencies do not generally accept these types of patients due to this reaction rate and associated liabilities. Additionally, some of these patients are not homebound and therefore would not qualify for a traditional certified home health visit. Given Medicare home health reimbursement, even if the patient is homebound, local home health agencies are not staffed or favorably inclined to provide a nursing service which lasts most of the work day for one full time equivalent. As an approved home health agency. Coram will provide this service for its immunotherapy patients which is otherwise unavailable for this population.
- First Dose Administration: Engaging a local home health agency to provide the first dose in a lengthy ongoing infusion therapy session is difficult at best as most do not have a first dose policy. Initiating infusion therapy services on a new patient requires specialized certified infusion

nurses, who are not regularly employed by Medicare certified home health agencies. These patients can be acute and complex or not homebound or low intervention. By providing the first dose at home, Coram can train the patient to self administer thus avoiding ongoing home health services for some of its patients. For others, Coram will meet this need by providing the required nurse to initiate therapy, first dose administration, then either continuing to treat the patient or turning the patient to the local home health agency if ongoing nursing care is required and a local home health agency is available and qualified for the service. As an approved home health agency, Coram will be able to expeditiously provide this service to effect a timely patient discharge from the hospital.

- Low Intervention Patients: These are patients who are not homebound and therefore do not qualify for Medicare/Medicaid home health services. They need the skilled nursing visit to initiate the infusion process and then train the patient to self administer. These patients are not seen by certified home health agencies as they don't generally qualify for services. It is these types of patients that stay in hospitals longer than necessary because they have to start infusion and be trained at the hospital due to lack of qualified home health agency availability. As an approved home health agency, Coram will admit these patients and train them to self administer, thus saving the system financially by avoiding prolonged hospitalizations.
- Three Dose Schedule: Patients on certain types of infusion are on a three dose schedule, 6 AM, 2 PM and 10 PM. Because of this schedule, many of these patients stay in the hospital extra day(s) because of the availability or lack thereof for nurses to be at home for the first dose, which may be at 10PM. Many home health agencies do not provide services nights and weekends. Likely home health hours are reported as 8AM to 5 or 6 PM and not on weekends, particularly to start a new patient. This impacts discharge dates from hospitals as well as first dose policy/training. In addition, short notice to these home health agencies for a late afternoon referral inevitably results in an extra day in the hospital. As an approved home health agency, Coram will treat these patients on an interim basis until the patient is trained to self administer or the local home health agency admits the patient.
- ➤ Rural and Pediatric Patients: It has also been Coram's experience with its infusion therapy patients, that those who reside in outlying counties the rural areas within the 25-county service area and pediatric patients are patients for whom it is difficult to obtain infusion nursing services. Coram will also fill this need when the situation arises.

Infusion nursing is highly specialized in protocol, equipment management, patient/family education and training and time commitment. These aspects of

home care delivery are not typical with the average Medicare certified home health agency patient profile and service delivery, or with their available nurse staff.

The service area definition proposed by the Applicant is defined at the county level. This was accomplished through thorough study of the Coram Memphis Branch Patient Records which includes the patients' counties of residence, referral sources (i.e. place of hospitalization) and the specialized needs as discussed above. The counties for which approval is sought, based on the patient evaluation and needs, are the following:

Benton	Gibson	Houston	Perry	
Carroll	Hardeman	Lake	Shelby	
Chester	Hardin	Lauderdale	Stewart	
Crockett	Haywood	Madison	Tipton	
Decatur	Henderson	McNairy	Wayne	
Dyer Henry		Obion	Weakley	
Fayette				

The guideline relative to 1.5 percent of the population requiring home health services is generally not applicable to the infusion therapy population. First, the average home health agency utilization in the defined service area is greater than 2.5 percent (not 1.5 percent as noted in the Guidelines). Second, the infusion population is a limited subset of that population or not included within that population at all. This relates to the fact that some of the patients are younger, not home bound and require start up and training for self administration, but not ongoing skilled visits.

Service Area Study: Typical Patient Profile versus Coram Patient Profile

A review of the Department of Health Division for Licensing Health Care Facilities indicates there are sixty one (61) home health agencies licensed to serve the Applicant's proposed service area. Evaluation of these 61 existing home health agencies serving the West Tennessee service area indicates these agencies are dramatically different than what is proposed via this CON application. Specifically, these Medicare certified home health agencies patient profile as provided in the Tennessee Joint Annual Report (JAR) Summary has the following characteristics:

- > Homebound
- Average visit duration is one to two hours
- Equipment generally not involved
- > 81 percent of patient counts are Medicare/Medicare HMO and TennCare

- > 80 percent of the visits are Medicare/Medicare HMO and 5 percent are TennCare, for a combined 85 percent of patient visits and 86 percent of revenues.
- ➤ 68 percent are 65 years of age and older with nearly 47 percent being 75 and older
- > Of total visits in the West Tennessee county agencies,
 - o 35 percent are physical, occupational and speech therapy,
 - o 18 percent are home health aide and homemaker services,
 - o 1 percent are medical social services, and
 - Just 44 percent are skilled nursing

Infusion nursing patients, and those proposed to be served by the Coram limited service home health agency, differ from the average Medicare certified home health agency patient. Notable differences are as follows:

- > The predominant age of patients is under the age of 65
- > Private insurance is the dominant payor
- > Specialty patient infusion visits last up to six hours one time per month for lengthy infusions of immunoglobin
- Antibiotic therapy and TPN patients can have up to three doses (infusions) per day at eight hour intervals
- > Nurses require specialized understanding and protocol for infusion equipment
- > The goal of infusion nursing is to train the patient to self administer with only limited follow up as needed by the nurse
- > The patient may not be homebound, but may not have reasonable geographic or financial access to reach an ambulatory infusion center, hospital or other venue for infusion
- ➤ Infusion therapy in the home is more cost effective to the system than accessing the product and service in an institution (i.e. a hospital)

The needs of this highly specific patient population with unique infusion therapy requirements is not being met in the most appropriate, accessible and available means. With Coram's approval for a limited service home health agency license, these access problems can be ameliorated.

Service Area Study: Existing Agencies

A list of the 61 home health agencies along with their patient volume for patients residing in the 25 county service area for each of the last three calendar years is provided in the following table.

Licensed Agency	County	2011	2012	2013	# of Svc Area
Professional Case Management of TN	Anderson	0	1	0	0
Tennessee Quality Homecare - NW	Benton	824	837	824	8
Baptist Memorial Home Care & Hospice	Carroll	235	213	260	8
Alere Women's and Children's Health	Davidson	1	1	1	1
Amedisys Home Hlth (Cumberland Bend)	Davidson	78	79	114	2
Elk Valley Health Services Inc	Davidson	47	50	74	19
Home Care Solutions, Inc	Davidson	29	18	7	1
Willowbrook Home Health Care Agency	Davidson	1	1	1	1
Tennessee Quality Homecare – SW	Decatur	1,195	964	912	8
Volunteer Homecare of West Tennessee	Decatur	1,299	1,260	1,313	9
Regional Home Care, Dyersburg	Dyer	744	814	707	6
NHC Homecare	Fayette	254	216	579	7
Where The Heart Is	Fayette	253	285	116	3
Amedisys Home Care (NHC in 2010)	Gibson	479	625	569	12
Volunteer Home Care, Inc	Gibson	2,486	2,975	3,000	12
Deaconess Homecare II	Hardin	1,117	1,153	1,216	9
HMC Home Health (Extendicare 2010)	Hardin	252	274	341	5
Regional Home Care – Lexington	Henderson	678	616	569	8
Henry County Medical Center Home Hith	Henry	354	401	363	5
Hickman Community Home Care, Inc	Hickman	2	0	3	1
Amedisys Home Health Care	Madison	2,489	2,586	2,741	18
Extendicare Home Health of West TN	Madison	962	993	0	0
Intrepid USA Healthcare Services	Madison	294	86	422	15
Lifeline of West Tennessee	Madison	0	0	1,085	20
Medical Center Home Health	Madison	1,403	1,617	1,706	14
Regional Home Care, Jackson	Madison	1,206	1,061	1,159	14
Careall Homecare Services	Maury	16	16	104	4
Maury Regional Home Services	Maury	4	4	1	1
NHC Homecare	Maury	31	22	50	4
Gateway Home Health Clarksville	Montgomery	84	176	82	2
Suncrest Home Health of Nashville, Inc.	Montgomery	53	32	42	2
Extendicare Home Health of Western TN	Obion	398	347	81	3
Amedisys	Overton	0	0	221	1
Highland Rim Home Health Agency	Putnam	0	0	4	1
NHC Homecare	Rutherford	0	0	88	1
Accredo Health Group	Shelby	9	14	12	1
Alere Women's & Children's HIth	Shelby	357	370	373	7
Amedisys Home Care	Shelby	882	938	1,061	3
Amedisys Home Health	Shelby	2,411	1,806	1,933	3
Amedisys Home Health Care	Shelby	576	683	936	3
Americare Home Health Agency	Shelby	1,324	1,727	1,811	2
Baptist Trinity Home care	Shelby	3,248	3,367	3,862	3
Baptist Trinity Home care - Private Pay	Shelby	1	1	0	0
Best Nurses	Shelby	311	366	364	
Elder Care	Shelby	780	341		1
Family Home Health Agency	Shelby			79	1
functional Independence Home Care		375	863	379	1
andional machemachice nome care	Shelby	725	804	953	3

Licensed Agency	County	2011	2012	2013	# of Svc Area Counties
Home Health Care of West Tennessee	Shelby	1,308	1,118	1,010	4
Homechoice Health Services	Shelby	2,037	1,164	861	6
Interim Healthcare of Memphis	Shelby	720	889	769	3
Intrepid USA Healthcare Services	Shelby	662	615	603	3
Maxim Healthcare Services	Shelby	103	197	155	6
Methodist Alliance Home Care	Shelby	2,958	2,939	2,935	3
No Place Like Home	Shelby	38	55	58	3
Senior Services Home Health	Shelby	642	697	609	1
Still Waters Home Health Agency	Shelby	105	127	101	1
Willowbrook Visiting Nurse Association	Shelby	473	533	479	5
Baptist Home Care/Hospice - Covington	Tipton	326	361	355	6
Prof'l Home Hlth Care (CareAll 2010)	Tipton	1,491	1,103	1,305	12
Careall Homecare Svcs/Univ. Home Hlth	Weakley	1,755	2,440	1,897	11
Guardian Home Care of Nashville, LLC	Williamson	44	47	49	2
Vanderbilt HC Affiliated w/ Walgreens IV	Williamson	0	0	3	2
Careall	Wilson	2	0	0	0
Magnolia Regl Hlth Ctr HH & Hospice	Out of State	39	53	43	2
Regional Home Care Parkway	Out of State	31	14	28	1
Total		41,001	41,356	41,778	10-5

Source: Joint Annual Report of Home Health Agencies, Attachment C, pages 6 through 10. Patients Serviced for the Service Area Counties per the Joint Annual Report Summary as reported in Report #6. The Number of Service Area Counties represent those counties within the Coram West Tennessee Service Area in which each home health agency had patients during 2013.

As the data above shows, many of these 61 agencies have very limited patient counts residing in the 25 county service area. Others may only serve 1 or a few of the 25 county service area. More importantly is the fact these HHA patients do not correlate with that proposed by this Coram CON application. Whereas 85 percent of the above agencies patient visits are Medicare/Medicare HMO and TennCare, Coram expects none of its patients to be Medicare and TennCare. Whereas the majority of the above agencies patients are 65 years of age and older, Coram expects its patients to be for the most part under the age of 65.

As discussed in this CON application, existing home health agencies are reluctant and refuse to treat many of these patients in their homes for a variety of reasons, mostly because the patients are not truly "home bound", they do not qualify for home care reimbursement. In other cases, the nature of the therapy, such as IVIG or Three Dose Therapies, which are either frequent throughout the day or require a several hour administration and observation, is not economically viable for existing HHAs to tie up a nurse for such low reimbursements. And finally, no existing HHA will consider administering First Dose Therapies and will only treat established infusion therapy patients.

Service Area Study: Existing Agency Service Availability

During the third and fourth quarter of 2013, Coram undertook a research study of the existing home health agencies within its proposed service area footprint to confirm each agency's skill set relative to infusion nursing. The purpose of this research was to identify resources to make Coram's pharmacy more effective, or in the alternative, to provide documentation supporting this CON application. The communication with the existing home health agencies was via telephone; not all agencies responded although a significant majority did. Following is a summary of the findings:

- ➤ IVIG: For the query as to whether the agencies provide nursing infusion services for IVIG patients, following were the responses of the 46 agencies which directly responded to this question:
 - > One half said they do not provide the service.
 - Another 35 percent indicated they could if they had the staff, had appropriate training and/or on a case by case basis.
 - Just eight agencies throughout the service area indicated 'yes'.

As will be noted in the further Service Area Study detailed below, 'yes' doesn't always mean yes. And, more importantly the 35 percent who indicated they could provide the service if they had the staff, had training or on a case by case basis do not currently provide the service.

- ➤ Alpha1: For the query as to whether the agencies provide nursing infusion services for Alpha1 patients, the answers were similar to IVIG with a few exceptions:
 - One half said they do not provide the service.
 - > Another one-third indicated they could if they had the staff, had appropriate training and/or on a case by case basis.
 - Four agencies indicated they could provide the service as long as cardiac therapies were not involved.
 - > Just six agencies throughout the service area indicated 'yes'.

As will be noted in the further Service Area Study detailed below, 'yes' doesn't always mean yes. And, more importantly those which indicated they could provide the service if they had the staff, had training or on a case by case basis do not currently provide the service, nor do those with the service qualifier relative to cardiac therapies.

- ➤ First Dose Therapies: For the query as to whether the agencies provide nursing infusion services for First Dose Patients, following were the responses of the 46 agencies which directly responded to this question:
 - > 87 percent do not provide the service.
 - > Another agency indicated they could if they had the staff.
 - > Just five agencies throughout the service area indicated 'yes'.

As will be noted in the further Service Area Study detailed below, 'yes' doesn't always mean yes.

The Applicant does not have specific letters from area home health agencies with respect to their limitations in service provision and corresponding support for this application. However, one of the agencies queried above with which Coram works regularly provided the following information in email format:

"...Methodist HH has historically not taken part in providing care for first dose or biologic infusions, you are correct. I think Coram is the right place to maintain this as a specialty function for their nurses trained in this procedure. Methodist does not plan to move in the direction of staffing for first dose or biologics in the home. ... While I am in favor of your nursing staff managing your first dose/biologic services, I am not sure my signing a letter of support for your HHA would be approved by Methodist - might be a bit of a conflict there. I would not actively oppose Coram seeking licensure, though, to serve this unique population."

The email is included in Attachment, Section C, Need: Home Health Services, Item 5. This information is a clear depiction of the existing situation relative to competition and existing providers. While the home health agency recognizes the importance of Coram's mission and service, no letter of support can be provided.

In line with this email, the Applicant does not believe any home health agency is going to admit that it is unable to perform any particular licensed home health agency service and provide a letter of support for this CON application in conjunction with that admission. However, the Applicant is unable to find anywhere in the enabling statute, promulgated regulations of the HSDA, the Guidelines for Growth or any criteria that requires an applicant for any CON regulated service produce documentation that existing providers lack interest in the services proposed to be provided by a CON applicant. The Applicant will supplement the record up to the hearing date upon receipt of any letters of support from any of the existing home health agencies.

Another query of the agencies due to Coram's familiarity with certain challenges relative to payor denials and home bound status (or lack thereof) was how each of the agencies handle Medicare denials. In most cases, the agency indicated they would bill the patient for denied service. This is, of course, a significant issue since the typical Coram patient as explained is not 'home bound' and therefore would normally be denied service without education of the payor source. Four recent patient examples of impact of not being homebound on a Medicare certified home health agency is presented in the following section.

Service Area Study: Pharmacy Patients Who Lost Home Health Coverage Due to Not Being Home Bound

As noted, Coram does not intend on becoming Medicare/Medicaid certified in its home health service. Because it will not provide the full range of home health services, it does not meet the Medicare conditions of participation. Additionally, many of its patients will not be home bound as defined by those conditions of participation, or other payors.

Because Coram provides the pharmacy products on an ongoing basis, with many of its patients being supported by existing licensed home health agencies, Coram often encounters specific patient scenarios and hardships associated with the patient's ongoing treatment needs. In recent months, Coram has documented four specific patient scenarios where the patient was being supported by a local home health agency but lost its home health agency coverage due to a midservice determination of not meeting the home bound status. Following is a summary of these four patient scenarios, which support the unique request by Coram to become a limited service home health agency for just these circumstances:

- Patient #1: Patient receiving Alpha1 therapy via a port. An existing HHA was supporting the patient's treatment. Payor began enforcing patients must be homebound. Payor discontinued the HHA service. In time, patient had to be taught to access his port and self infuse his own port.
- Patient #2: Patient receiving Alpha1 therapy. Agency has been starting line and taught patient to mix drug and self infuse then agency left. Agency was in home approximately 30 minutes per visit. Patient works in Memphis but lives in Mississippi. To go to an ambulatory infusion suite, patient would have to miss at least half day of work. Coram was able to help the insurance company see the total financial out of pocket it would pay a suite versus what it is actually paying the agency. This coupled with the fact the patient's employer needs patient present at work as patient is one of only two people who do patient's job. Patient needs job for benefits. Finally insurer reversed HOMEBOUND decision and let patient keep benefits.
- ➤ Patient #3: Patient was receiving Alpha1 therapy. Patient has job and was therefore deemed not home bound by payor. Patient appealed agency decision. Payor indicated for patient to obtain a letter of medical necessity but for patient to pay for care of home health service. Coram negotiated a lower rate for the patient subsidizing some of the cost on the patient's behalf.
- Patient #4: Patient was receiving Alpha1 therapy and as a result experienced less infections. Patient began working part time. The payor

reversed coverage since now not homebound. Patient unable to find an agency willing to teach him to self access with an INT/butterfly. Since Coram has protocols in place for hemophiliac program, Coram was able to perform training provided the patient had a support person to also get trained. Because there was not a CON in place in this geographic area, this patient traveled to the Coram suite in Nashville, where he received the required training and support. The patient has infused his patient medication since then without difficulty.

As with each of these cases, homebound status was a factor in discontinuing the patient's treatment by a home health agency. Coram facilitated in these instances including coordinating treatment within Coram's Nashville infusion center (some distance away), presenting the case to the payor, and assisting in subsidizing the home treatment on the patient's behalf. If Coram had been licensed as a limited service home health agency, Coram would have worked effectively and expediently to appropriately train the patient to self administer.

Service Area Study: Patients Requiring Home Health Agency Services

Patients currently referred to Coram for pharmacy products fit into one of the product categories described above. Many of these patients who are typical therapy patients are referred by the physician or hospital with home health, if necessary, in place. The more challenging patients are those referred to Coram for pharmacy products which are first dose, specialty infusion (IVIG, Alpha1), multiple times per day infusions or low dose interventions.

For these patients who are referred to Coram pharmacy *without* a needed home health service, beginning in June 2013, Coram initiated telephone documentation of the requirements that became imposed on Coram to meet the patient's needs with an effective discharge from the hospital (as most of these patients were hospitalized). For these patients without necessary home health support for which Coram undertook the challenge to find the requisite resources for the patient, Coram documented the situation. The following table presents a summary of the documentation from June through March 2014:

	Number of	Coram Initiativ	es to Identify Hom	e Health Service
	Patients Referred	Home Health	Delayed Home	
	without Home	Identified	Health	No Home Health
Month/Year	Health	Timely	Identification	Identified
June 2013	16	8	2	6
July 2013	20	6	12	2
August 2013	23	13	6	4
September 2013	12	3	8	1
November 2013	13	4	8	1
December 2013	20	8	11	1
January 2014	22	15	6	1
February 2014	17	11	5	1
March 2014	12	3	9	0
9 Month Total	155	71	67	17
Average/Month	17	8	7	2
Percent	240	46%	43%	11%

Note: Data was not captured during the month of October 2013 due to personnel changes.

As presented in the above table, only 46 percent, or about 4 ½ of 10 patients received home health services on a timely basis. Eleven percent did not receive the service so alternative treatment was pursued. The balance, 43 percent of patients, had delayed access to treatment.

In sum, 5 ½ of 10 patients (54 percent) requiring medically necessary services did not receive services on a timely basis, had delayed discharges from the hospital or did not receive the service in the most effective and appropriate

manner. This is clearly a deficiency in the healthcare delivery system that needs to be addressed; and, it can be appropriately remedied with the approval of Coram's limited service home health agency via this CON application.

Service Area Study: Patient Case Study

Coram regularly works with its pharmacy patients to understand their needs and how they may be best met in an efficient, cost effective and expeditious manner. Patients who have an understanding of resources that are NOT available to meet their needs can be valuable in sharing their "story" with HSDA so that Coram may receive CON approval. Certain Tennessee patients of Coram's pharmacy business have agreed to "provide their story" in the form of a letter. Following are the stories:

- Michelle B: "I am a nurse who is also a long term Total Parenteral Nutrition (TPN) patient. My personal experiences and my clinical knowledge are presented here to share with you why it is so very important that your Agency approve Coram's request for a limited service home health agency. By way of background, I travel extensively and am involved in a patient advocate program. Because of my personal history with access maintenance and having to have a line replaced while out of the country in the past, I requested a PICC line repair kit from Coram. Coram provides my TPN products. Coram had the kit available and the requisite program and educational material. However, because the Memphis branch did not have a CON to provide skilled nursing services, the nurses at the branch could not 'touch' me nor provide me with the skilled nursing training. Therefore, I went without this valuable resource. Sure enough, about two months later, I experienced a fracture on the pigtail portion of my line that resulted in what I consider an unnecessary procedure. Had Coram had its limited home health agency license, the healthcare systems costs would have been less as (1) I would not have had to had an extra procedures; (2) I could have fixed the problem without outside intervention; (3) the quality of my treatment and experience would have been improved; and (4) outcomes would have been improved. From a personal standpoint, the additional costs I incurred and additional hardships and recovery from the procedure I had to endure would I would have also had better patient outcomes, have been avoided. improving the quality and cost effectiveness of my care and treatment. For the reasons as stated above, and my knowledge of Coram's commitment to quality service, please approve Coram's CON request for a limited service home health agency. Please contact me if I can be of further assistance."
- Patient B.H.'s story: I am the Regional Nurse Manager with Coram Alternate Site Services, Inc. We recently had a patient Mrs. B. H. whose husband, Mr. H., was her primary caregiver. Mrs. B.H. was a terminal patient who has since expired. We met Mrs. B. H. while a patient in a local hospital. The hospital had arranged for Coram to provide Mrs. B. H. with the infusion products and a home health agency to provide the at home skilled infusion services. Upon accepting the patient, Coram nurses saw the patient in the hospital, doing the pump connection and line assessment as is the standard of care for this type of patient. Mrs. B. H. then went home. One of Coram's

standard protocols is conduct a 24 hour follow up by telephone with each patient. During this callback the day after doing the pump connection and line assessment, the family answered the telephone. They informed the Coram representative that the contracted home health agency was still there and having difficulty accessing the port. In fact, we were informed that two nurses had attempted with three different needles. Obviously, both Mrs. B. H. and Mr. H. were quite concerned and fearful of the circumstance. In response, Coram nurses took additional supplies to the patient home and provided one on one education on the spot for the nursing agency nurse. Our Coram staff talked the nurse through the appropriate technique for successfully accessing The situation was very unfortunate for Mr. and Mrs. H. encounter with the healthcare system was suboptimal and the level of care received was below acceptable quality. Had Coram been licensed to provide this level of skilled care for this unique infusion patient type, there would have been many benefits to the patient and healthcare system in general. The patient would have had improved patient experience; the patient would not have had two nurses with three different needles; the patient's outcome would have been better; the patient would have received treatment consistent with the standard of care: the patient would have had less stressors in this circumstance although we do not know the ultimate impact of that improvement on the health and longevity of the patient. From a general healthcare perspective, had Coram provided the service from the outset, it would have been more cost effective as Coram came to the patient home to educate the other home health agency on treatment methods - so now extra nurse skills were used to treat the patient; quality of care would have been improved as a result of eliminating the failed attempts to access the port; and patient experience with the healthcare system would have been improved. It is circumstances like this that necessitate the need for Coram to have its certificate of need application to provide limited scope home health services be approved. Please give our request favorable consideration."

Service Area Study: Patient Placement Hardships

Brief summaries of some of the patients having delayed or no access to care (the 54 percent group) which are summarized in the prior discussion are detailed below. As noted, there were 84 patients falling into this category in these limited months. This is just a snapshot of some of those stories.

- Patient A, aralast: 12 contacts; all 12 declined service due to not being able to provide this therapy (4), cannot provide in that location (6) and other reasons (2). Agencies declining this patient included Girling, Amedisys, Gentiva, Advanced HomeCare, Interim and Laughlin.
- ▶ Patient B, Blue Cross patient, requires catheter care: 5 contacts; all 5 declined due to not homebound, compliance, and not in network. Agencies declining service included Homechoice, Amedisys, HHC of West Tennessee and Baptist.
- ➤ Patient C, Blue Cross patient, pharmacy prescription for amphotericum B: four contacts; all 4 declined service due to high risk of drug reaction and not enough notice to prepare for service. Declining agencies included Sta Home, Intrepid USA and Methodist.
- Patient D, Blue Cross patient, pharmacy prescription for IVIG: 15 contacts, all unsuccessful. Reasons for not accepting patients include do not accept pediatric patients, out of service area, or no reason. Declining agencies included Magnolia, Homechoice, Sta Home, Intrepid, Functional Independence, Amedisys, Methodist, AmeriCare, Maxim, Still Waters, Willowbrook, Best Nurses and Visiting Angels.
- Patient E, Americhoice, pharmacy prescription for daptomycin: 7 contacts, all declined for out of network or staffing. Declining agencies included Amedisys, Trinity, WTHI, Methodist, HHC of West Tennessee and Homechoice.
- ➤ Patient F, pharmacy prescription fo zosyn: 6 contacts; five denied for staffing or out of network. Declining agencies WTHI, Methodist, Baptist, Homechoice and Americare.
- ➤ Patient G, Medicare, pharmacy prescription for IVIG: six contacts; five declined due to staffing and can't provide this therapy. Declining agencies included Homechoice, Baptist, Primecare, Sta Home and Intrepid.
- ➤ Patient H, pharmacy prescription for IVIG: eight contacts, all denied service. Reasons given were can't provide therapy, not staffed or out of area. Declining agencies included Amedisys, Intrepid, Homechoice, Careall, Harden County and Regional Homecare.

- ➤ Patient I, prescription for IVIG: 9 contacts all declined due to not providing therapy, not staffed, out of area or no reason given. Declining agencies included Amedisys, Functional Independence, Intrepid, WTHI, Sta Home, Interim, Primcare and Methodist.
- ➤ Patient J, Blue Cross, prescription for ABX: six contacts, five denied due to no staffing and no first dose. Denying agencies included Amedisys, Methodist, Baptist, Homechoice and HHC of West Tennessee.
- ➤ Patient K, Healthsprings of Tennessee, prescription for ABX: four contacts, three denied due to staffing issues. Denying agencies included Careall, HHC of West Tennessee and Functional Independence.

Additional details of these patient situations and the balance of the other patient encounters summarized in the June 2013 through March 2014 documentation are available upon request, subject to HIPAA regulations.

Coram's proposed home health agency will address the system limitations created by the documented gap in the delivery system. Coram recognizes it can correct these deficiencies as each of the patient scenarios detailed above could be remedied with the approval of this CON application, and would not have occurred had Coram been licensed as a limited service home health agency.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED:

NEED: HOME HEALTH SERVICES

2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county. The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

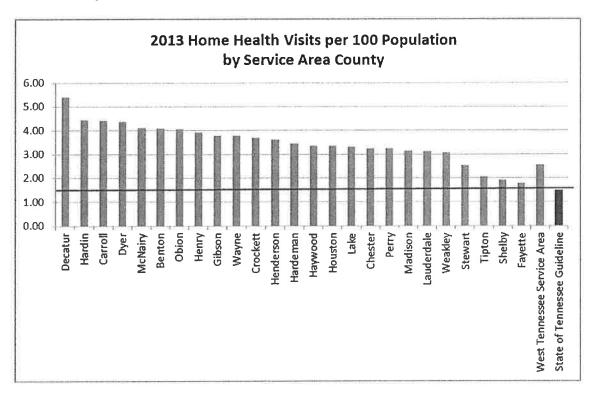
The defined service area for Coram Alternate Site Services, Inc.'s proposed home health agency includes 25 counties within West Tennessee. This area represents the counties where in excess of 86 percent of Coram's Tennessee (instate) infusion therapy patient population resides.

In the following table is the current (2013) population as estimated by the Tennessee Office of the Governor, forecasted four years from current to 2018. Accompanying the population count is the home health formula identifying potential home health patients as a 1.5 percent general guideline applied to the total population.

Service Area	Рори	lation	1.5 Percent General Guideline		
County	2013	2018	2013	2018	
Benton	16,315	16,104	245	242	
Carroll	28,213	27,831	423	417	
Chester	17,355	17,999	260	270	
Crockett	14,568	14,683	219	220	
Decatur	11,773	12,080	177	181	
Dyer	38,205	38,427	573	576	
Fayette	40,081	44,888	601	673	
Gibson	50,748	52,163	761	782	
Hardeman	26,492	26,067	397	391	
Hardin	25,968	26,244	390	394	
Haywood	18,199	18,009	273	270	
Henderson	28,080	28,631	421	429	
Henry	32,595	32,956	489	494	
Houston	8,358	8,447	125	127	
Lake	9,795	9,468	147	142	
Lauderdale	27,465	27,125	412	407	
McNairy	26,408	27,299	396	409	
Madison	99,153	101,001	1,487	1,515	
Obion	31,536	31,222	473	468	
Perry	7,971	8,096	120	121	
Shelby	940,972	954,012	14,115	14,310	
Stewart	13,436	13,941	202	209	
Tipton	63,001	67,545	945	1,013	
Wayne	16,887	16,724	253	251	
Weakley	38,255	39,491	574	592	
West TN					
Service Area	1,631,829	1,660,453	24,477	24,907	

Source: Tennessee Department of Health, Office of Policy, Planning and Assessment, Division of Health Statistics, 2014 Revision.

The above computes an estimated 24,900 persons who are appropriate for home health services, based on the general guidelines. Actual experience within these 25 counties far exceeds the need estimate based on 1.5 percent. In fact, none of the service area's 25 counties have a use rate less than 1.5 percent. Use rates in the 25 counties range between 1.78 percent and 5.42 percent. Actual 2013 use rates by service area county are shown in the following chart:



The overall average of the service area is 2.55 percent, which is 70 percent greater than the 1.5 percent guideline. Had the actual historical utilization been utilized to forecast the demand in 2018, the estimate 24,900 visits in 2018 would have increased to more than 42,300-70 percent more than the computation utilized by the State to determine need presented in the above table.

Not a single county in the West Tennessee Service Area had actual utilization experience of 1.5 percent or less; the lowest utilization as noted is 1.78, 19 percent greater in one county than the State formula with all remaining counties exceeding, some materially, this 1.78 value. This demonstrates the State's need formula of 1.5 percent of population is a dated formula not incorporating the healthcare system's focused initiative to provide healthcare services to patients in the least restrictive, least costly appropriate environment. Focus on community based programs and services, outpatient treatment and effectively treating patients in a less costly environment all contribute to the 1.5 guideline rate being an inappropriate measure of the need for home health services.

Coram's proposal involves providing services to approximately 228 patients per year. This represents only 0.9 percent of the 24,907 in the table or 0.5 percent of the actual/expected 42,322 identified patients if the total is inclusive of the infusion patient.

Aside from actual experience in the service area far exceeding the 1.5 computation, in the case of this CON application for a restricted home health service license, the general guideline is not applicable as the proposed patient population is not the traditional home health client, nor is the person seen for the same length of time. The population in need of infusion nursing services is generally not elderly, not covered by Medicare, not in need of the full scope of home health services and may not even be homebound. The patient, however, will be a costly addition to the healthcare system if the infusion service is provided in an institutional setting versus at home. Furthermore, part of Coram's proposal is to educate the infusion patient to enable self administration after the initial visit(s). Therefore, further reduction in costs to the healthcare system will be expected with the approval of this CON application.

NEED: HOME HEALTH SERVICES

3. Using recognized population sources, projections for four years into the future will be used.

The defined service area for the Applicant is 25 counties within West Tennessee. These counties include those listed in the table below which also provides forecasted population as estimated by the Tennessee Office of the Governor, four years from current (2014), the forecasted change between 2013 and 2018 and the percent that change represents.

Service Area Population		Change from	2013 to 2018	
County	2013	2018	Count	Percent
Benton	16,315	16,104	(211)	-1.3%
Carroll	28,213	27,831	(382)	-1.4%
Chester	17,355	17,999	644	3.7%
Crockett	14,568	14,683	115	0.8%
Decatur	11,773	12,080	307	2.6%
Dyer	38,205	38,427	222	0.6%
Fayette	40,081	44,888	4,807	12.0%
Gibson	50,748	52,163	1,415	2.8%
Hardeman	26,492	26,067	(425)	-1.6%
Hardin	25,968	26,244	276	1.1%
Haywood	18,199	18,009	(190)	-1.0%
Henderson	28,080	28,631	551	2.0%
Henry	32,595	32,956	361	1.1%
Houston	8,358	8,447	89	1.1%
Lake	9,795	9,468	(327)	-3.3%
Lauderdale	27,465	27,125	(340)	-1.2%
McNairy	26,408	27,299	891	3.4%
Madison	99,153	101,001	1,848	1.9%
Obion	31,536	31,222	(314)	-1.0%
Perry	7,971	8,096	125	1.6%
Shelby	940,972	954,012	13,040	1.4%
Stewart	13,436	13,941	505	3.8%
Tipton	63,001	67,545	4,544	7.2%
Wayne	16,887	16,724	(163)	-1.0%
Weakley	38,255	39,491	1,236	3.2%
West TN Service Area	1,631,829	1,660,453	28,624	1.8%

Source: Tennessee Department of Health, Office of Policy, Planning and Assessment, Division of Health Statistics, 2013 Revision.

Given the Applicant's forecasted skilled nursing patient count and skilled nursing patient visits, it only expects to annually admit 0.014 percent of the total population (228 / 1,631,829) based on 2013 population counts, decreasing to 0.0137 percent based on 2018 population counts.

As noted previously, this application is for a limited service (restricted) home health agency to provide infusion nursing and related services to infusion therapy patients in their home. It is a special circumstance and category of patient who does not fall within the traditional home health type patient. Accordingly, its need should be measured by the special circumstances demonstrated by the Applicant, not the traditional or general observations included in the Guidelines.

Service area maps have been prepared for this project and are included in Attachment, Section B, Project Description, Item V and Attachment C, Home Health Services, Item 3. There are two maps included. The first one is the entire state with the service area counties highlighted. The second version has the service area "zoomed in" to provide more detail at the county level.

There are no readily available infusion nursing services to meet the unique needs of the Coram infusion therapy patients. Time and time again, Coram and its referring hospitals struggle with this dilemma resulting in extended but avoidable hospital stays of these patients. Constituent input supporting this fact is presented in response to Question 5 below.

NEED: HOME HEALTH SERVICES

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rates as calculated in the Joint Annual Report of existing home health agencies in the service area. Based on the number of patients served by home health agencies in the service area, an estimate will be made as to how many patients could be served in the future.

Home health agencies with licenses in each county do not necessarily provide services within the counties for which they are licensed. As required in the Joint Annual Reports (JAR), each home health agency is to identify its patients by county of residence. So, for example, an agency licensed in 15 counties may not have patients in all 15 counties. And, by being licensed in those 15 counties, the JAR Summary will list "licensed" agencies and "reporting" agencies indicating that although licensed each is not reporting services to residents of each county in which it is licensed.

The following table identifies the number of licenses by county along with those agencies providing reports and reporting residents by county.

Service Area Counties	Number of Home Health Agencies			
	Licensed	Reporting		
Benton	11	10		
Carroll	13	13		
Chester	14	13		
Crockett	13	12		
Decatur	17	14		
Dyer	11	10		
Fayette	26	23		
Gibson	15	14		
Hardeman	17	15		
Hardin	16	14		
Haywood	15	13		
Henderson	14	13		
Henry	10	10		
Houston	12	11		
Lake	6	5		
Lauderdale	14	11		
McNairy	15	13		
Madison	16	15		
Obion	12	12		
Perry	11	6		
Shelby	27	27		

Service Area Counties	Number of Home Health Agencies			
	Licensed	Reporting		
Stewart	10	10		
Tipton	26	22		
Wayne	11	9		
Weakley	13	11		

Source: Tennessee Department of Health, Office of Policy, Planning and Assessment, Division of Health Statistics.

The total of the table will not indicate how may home health agencies are licensed within the 25 county area. A cumulative total will actually provide the aggregate number of counties. So in the example where one home health agency is licensed in 15 counties, it is counted 15 times in the above list. In the case of this CON application proposed service area, there are 61 licensed agencies serving one or more counties in this service area.

Considering just the active home health agencies and patients by county of residence, and the 2013 utilization by county, the effective use rate averages 25.5 patients per 1,000 population, or 2.55 percent of the population. As shown in the following table, all of the 25 counties have use rates exceeding the State guideline. These range from a low of 1.78 percent to a high of 5.42 percent depending on the county of residence.

Service	Patients	2013	Use Rate	2018	Estimated 2018
Area	Served in	Population		Population	Capacity
County	2013			·	
Benton	667	16,315	0.0409	16,104	658
Carroll	1,246	28,213	0.0442	27,831	1,229
Chester	563	17,355	0.0324	17,999	584
Crockett	537	14,568	0.0369	14,683	541
Decatur	638	11,773	0.0542	12,080	655
Dyer	1,671	38,205	0.0437	38,427	1,681
Fayette	713	40,081	0.0178	44,888	799
Gibson	1,924	50,748	0.0379	52,163	1,978
Hardeman	917	26,492	0.0346	26,067	902
Hardin	1,157	25,968	0.0446	26,244	1,169
Haywood	612	18,199	0.0336	18,009	606
Henderson	1,015	28,080	0.0361	28,631	1,035
Henry	1,283	32,595	0.0394	32,956	1,297
Houston	281	8,358	0.0336	8,447	284
Lake	325	9,795	0.0332	9,468	314
Lauderdale	857	27,465	0.0312	27,125	846
McNairy	1,089	26,408	0.0412	27,299	1,126
Madison	3,121	99,153	0.0315	101,001	3,179
Obion	1,280	31,536	0.0406	31,222	1,267
Perry	258	7,971	0.0324	8,096	262
Shelby	18,064	940,972	0.0192	954,012	18,314
Stewart	339	13,436	0.0252	13,941	352
Tipton	1,298	63,001	0.0206	67,545	1,392
Wayne	640	16,887	0.0379	16,724	634
Weakley	1,180	38,255	0.0308	39,491	1,218

Service Area County	Patients Served in 2013	2013 Population	Use Rate	2018 Population	Estimated 2018 Capacity
Total	41,675	1,631,829	0.0255	1,660,453	42,322

Source: Tennessee Department of Health, Office of Policy, Planning and Assessment, Division of Health Statistics, 2014 Revision.

As the table in response to Section C, Need, Question 5 indicates, there are actually 61 agencies reporting activity in 2013 in these counties. Yet, despite this number of agencies, there is a compelling need for approval of Coram's proposal for infusion nursing services. The distinct and highly specialized need with credentialed certified staff is unique when one considers the existing home health agencies serving West Tennessee. Their provision of services does not generally include first dose protocols or certified infusion staff, but rather focuses on Medicare clients in need of skilled, aide and therapy visits.

NEED: HOME HEALTH SERVICES

- 5. Documentation from referral sources:
 - a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.
 - b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.
 - c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.
 - d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

The patients to be treated by Coram will be its home infusion product patients in need of administration of the infusion product and related infusion nursing services. By way of example and not limitation, the related services are line maintenance, infusion equipment repair and replacement and dressing changes on central lines and external access ports. These services will be provided by a registered nurse who is appropriately credentialed and is certified with a CRNI designation (certified registered nurse infusion). These services and credentials are a unique service and not typical of the average Medicare certified home health agency available to West Tennesseans.

The types of patients will be restricted to infusion therapy patients. Types of infusion products to be administered include:

- Antibiotics
- ➤ Total parenteral nutrition (TPN)
- > Hydration
- Cardiac products (such as inotropic therapies)
- > Intravenous immunoglobulin (IVIG) and other similar specialty drugs
- > Pain management
- > Antiemetic
- > Steroids

The uniqueness of this patient population that drives the need for Coram to be licensed as a home health agency includes the following infusion patients by group:

- Specialty Patients Requiring IVIG and Alpha 1 Therapies
- > First Dose Administration
- Low Intervention Patients
- > Three Dose Schedule Patients
- > Rural and Pediatric Patients

The underlying bases and discussions relative to the lack of access and availability of skilled nursing services for this patient population are provided in response to Section C, Need: Home Health Services, Question 1. In summary, each of these patient types requires and will benefit from infusion nursing services in the home which includes patient and family education for self administration.

To estimate the number of infusion nursing patients and their related skilled visits for the forecast period, the Applicant considered the types of infusion therapy products which comprise the patient therapies for which it has physician orders, the average monthly census by type of infusion and the hardship the Applicant has encountered in various situations throughout West Tennessee in obtaining qualified infusion nursing services from other third parties. This affected the analysis because Coram is not intending on competing with existing available services but rather responding to a community need based on the gap in service which equates to a lack of availability or accessibility of infusion nursing services.

As noted previously, there are primary differences between two types of Coram patients. One is the more typical infusion therapy patient receiving antibiotics, TPN, pain management, cardiac and the like; the other is the specialty patient receiving immunoglobin or alpha 1 therapies. Following is a table that reflects the number of therapies by quarter for the most recent calendar year:

Therapy	Q1-2013	Q2-2013	Q3-2013	Q4-2013	CY 2013
Antiobiotics	90	92	93	60	335
Anticoagulant Therapy	0	0	0	1	1
Antiemetic	4	3	3	1	11
Antiviral Antifungal Agents	5	8	3	1	17
Aralast Alpha-Proteinase Inhibitor	5	5	4	7	21
Calcitonin	1	2	1	0	4
Cardiovascular Agent	4	3	4	4	15
Catheter Care	11	10	13	10	44
Corticosteroid Therapy	2	0	6	3	11
Gastrointestinal Tract Agent	1	0	0	0	1
Immunoglobulin IV	13	15	17	18	63
Immunoglobulin Subcutaneous	10	7	8	9	34
Investigational Drug	1	1	0	0	2
IV Fluid Replacement, Hydration	8	11	7	4	30
Misc IV Drugs	4	1	1	0	6

Therapy	Q1-2013	Q2-2013	Q3-2013	Q4-2013	CY 2013
Multiple Sclerosis Injection	1	0	0	0	1
Opiate Pain Management	6	5	5	4	20
TPN	68	68	59	79	274
Zemaira Alpha Proteinase Inhibitor	6	7	7	8	28
Total	240	238	231	209	918

The more common therapies comprise 84 percent of Coram's deliverables; the specialty patients comprise 16 percent of the Memphis Branch of therapies provided. In terms of estimated requirement for infusion nursing services, it is estimated that 100 percent of the specialty patients will require the service. Depending on the therapy, the service could be an initial treatment covering several days and then once per month; others may be three visits at start of care then only annual reevaluation. The number of visits is dependent on the therapy regimen and the treatment duration (i.e. for life or some shorter time frame). The reason for such high utilization is these patient infusions last up to 6 hours per treatment and/or the patient is not homebound. As such, the more traditional home health agency providing intermittent services for the homebound is not generally staffed for nor compensated for under Medicare guidelines such long nursing visits. Ongoing, Coram has significant challenges to find nursing services for these patients resulting in these patients remaining in the hospital for an unnecessary prolonged period, having the patient travel to his/her physician office for Coram to meet the patient in that setting or having the patient travel to another licensed location - all creating hardship on the patient and family.

For the balance of Coram's therapy patients, it is estimated that 5 percent of those patients will require infusion nursing provided by Coram's home health agency. Similarly, this patient estimate is based on the Applicant's assessment of its patient case load and the challenges it regularly faces in admitting a patient to the pharmacy service that cannot obtain at home support to initiate the infusion therapy. Depending on the therapy, each patient will receive four visits per month on average.

Extrapolating the above utilization assumptions and applying them to the estimated future monthly census of infusion therapy patients results in a computed approximate 22 percent of Coram's pharmacy patients requiring skilled nursing services be provided by Coram. Coram herein provides the information and patient counts/visits regarding the types of cases that it will treat as part of its home infusion nursing services. All home health visits will be skilled nursing as noted in the following table:

Factor	Year One	Year Two
Number of Home Health Patients	207	228
Skilled Home Health Visits by Infusion Therapy	Type	//
Aralast Alpha-Proteinase Inhibitor	300	330
Immunoglobulin IV	277	305
Immunoglobulin Subcutaneous	150	165
Investigational Drug	66	73
Zemaira Alpha Proteinase Inhibitor	400	440
Other Specialty	31	33
Subtotal	1,224	1,346
All Other (TPN, Antibiotics, Etc)	551	606
Total Annual Skilled Nursing Visits	1,775	1,952

Regarding support from the provider community, the Applicant has received letters of support from existing infusion therapy referral sources who recognize the need for Coram to be licensed to realize more effective and appropriate hospital discharges. These letters include specialty physicians, patients and others. Sentiments from these letters supporting the need for this CON application's approval include the following:

- "...The typical home health agency nurse, not certified in Infusion Services, does not understand the importance of pharmokinetics like the Coram nurses do. ... impacted my patient... This example is not in isolation; I regularly have other such circumstances."
- "...It is important to me that Coram's requested certificate of need be approved This will improve by patient's quality of care and these patient outcomes."
- "...I am well aware that Coram spoke with eleven different agencies all of whom denied me the needed training and treatment. This delay caused my much anxiety. I can't imagine that it didn't also increase my treatment costs to the healthcare system."
- "...Having treatment needs is hardship enough on a patient. Not being able to reasonably access treatment in a timely manner is even worse."
- "...Had Coram had its limited home health agency license, the healthcare systems cots would have been less as (1) I would not have had to had an extra procedure; (2) I could have fixed the problem without outside intervention; (3) the quality of my treatment and experience would have been improved; and (4) outcomes would have been improved."
- "...the additional costs I incurred and additional hardships and recovery from the procedure I had to endure would have been avoided."

- "...My patients who require immunoglobulin therapy do not have adequate services available to them..."
- "...When my patients who require IVIG therapy, and the most appropriate quality of care site to administer is the home, the availability of this service is virtually non-existent."
- "...The licensed home health agencies serving our area are not proficient in IVIG therapy, are not familiar with first dose protocols and are generally not available to provide a nursing visit that lasts five to six hours which my patients require."
- "...Typically, the patient I am referring (to Coram) carry the diagnosis of primary immune deficiency. As you can understand, it is in general in the patient's best interest, with hypogammaglobulinemia, to avoid hospital settings and sick contact. An ideal approach is for these patients to have treatments provided in the home when possible. Unfortunately, it is rare to find a home health agency willing to provide these services in the home, especially for pediatric patients. It is even a more difficult problem to find a home health agency willing to provide infusion nursing services for specialized infusion products such as IVIG, typically due to lack of qualified nursing or inexperience in dealing with patients carrying diagnoses of primary immune deficiency."
- "...I have dealt with Coram in the past; and the need for skilled nursing services for this population of patients is a current great need that is inadequately met."

Please refer to Section C, Home Health Services, Item 5 for the letters of support provided by referral sources and these other knowledgeable parties in the service area.

It is clear from these letters that the appropriate home infusion nursing services required by these infusion therapy patients is not readily available throughout the West Tennessee service area. Existing agencies do not meet the needs of these patients, due to the fact that some of the services do not qualify for Medicare/Medicaid provision meeting the conditions of participation; some of the services are so atypical of the reimbursement methodology associated with short term intermittent nursing treatment; and some of the nursing services are a relocation of in hospital care to the patient home to provide a more cost effective, patient oriented service.

Approving the Coram CON application for a restricted home health license will have a positive effect on the quality of care available to the area population, will improve the discharge options available to area hospitals, will enhance quality of care through more prompt and cost effective discharge of patients and will meet a demonstrated need for infusion nursing services throughout the region.

NEED: HOME HEALTH SERVICES

- 6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
 - a. The average cost per visit by service category shall be listed.
 - b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The average cost per skilled nursing visit for the Applicant is forecasted to be \$133 in 2015 (year one) dollars. This is computed based on taking projected data chart total costs and dividing by the number of visits. It is based upon a mix of patients as described previously with some portion of the visits lasting up to six hours, or three times as long as the typical visit duration. Evaluating cost per visit based on the typical visit versus the six hour visit, the Applicant's estimated costs per visit are approximately \$116 and \$348, respectively.

In considering the charge per visit of home health agencies operating within the service area, the average for a skilled nursing visit for the agencies listed in response to Section C, Need, Question 5, per the 2013 Joint Annual Report Summary had a range per skilled visit from a low of \$81 to a high of \$155. Only eight agencies reported this information which is provided by agency in the following table:

2013 Charge Per Skilled Visit
\$90
\$90
\$120
\$120
\$90
\$155
\$95
\$81

Source: Report 3 from the 2013 Joint Annual Report Summary.

The above averages \$105 per visit in 2013 dollars. This contrasts with the charge per visit of \$150 proposed by the Applicant. Adjusting for two years inflation to be presented in 2015 dollars increases the above average to approximately \$116 per visit.

In terms of cost per visit, the same Report 3 from the Joint Annual Report Summary provides cost per visit for skilled care. Thirty nine agencies reported this information which is presented in the following table:

Fennessee Quality Homecare – Northwest (Benton) Baptist Memorial Home Care (Carroll) Fennessee Quality Homecare – Southwest (Decatur) Volunteer Homecare of West Tennessee, Inc. (Decatur) Regional Home Care, Dyersburg (Dyer) NHC Homecare (Fayette) Where The Heart Is, Inc. (Fayette) NHC Homecare (Gibson) Volunteer Home Care, Inc. (Gibson) Deaconess Homecare II (Hardin) HMC Home Health, LLC (Hardin) Regional Home Care, Lexington (Henderson) Henry County Medical Center Home Health (Honry) Amedisys Home Health Care (Madison) Intrepid USA Healthcare Services (Madison) Regional Home Care, Jackson (Madison) Extendicare Home Health of Western Tennessee (Obion) Amedisys Home Care (Shelby) Amedisys Home Health Care (Shelby) Amedisys Home Health Agency, Inc. (Shelby) East Nurses, Inc. (Shelby) Extended Health Care, Inc. (Shelby)	\$53 \$312 \$47 \$81 \$101 \$128 \$53 \$99 \$88 \$160 \$109 \$60 \$158 \$43 \$153
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amily Home Health Agency (Shelby)	\$135
unctional Independence Home Care, Inc. (Shelby)	\$160
Iome Health Care of West Tennessee, Inc. (Shelby)	\$98
IomeChoice Health Services (Shelby)	\$87
nterim Healthcare of Memphis, Inc. (Shelby)	\$70
ntrepid USA Healthcare Services (Shelby)	\$136
lethodist Alliance Home Care (Shelby)	\$160
enior Services Home Health (Shelby)	\$130
till Waters Home Health Agency (Shelby)	\$70
Villowbrook Visiting Nursing Association, Inc. (Shelby)	\$130
aptist Home Care and Hospice – Covington (Tipton)	\$197
areAll Homecare Services (Tipton)	
areAll Homecare Services (Weakley)	\$69

Source: Report 3 from the 2013 Joint Annual Report Summary.

The above averages \$111 per visit in 2013 dollars. This contrasts with the cost per visit of \$133 proposed by the Applicant which is higher due to the long length of the specialty visits, i.e. 5 to 6 hours.

NEED

- c. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)
 - (4) Applications for Change of Site. When considering a certificate of need application which is limited to a request for a change of site for a proposed new health care institution, the Commission may consider, in addition to the foregoing factors, the following factors:
 - (a) Need. The applicant should show the proposed new site will serve the health care needs in the area to be served at least as well as the original site. The applicant should show that there is some significant legal, financial, or practical need to change the proposed new site.
 - (b) Economic factors. The applicant should show that the proposed new site would be at least as economically beneficial to the population to be served as the original site.
 - (c) Contribution to the orderly development of health care facilities and/or services. The applicant should address any potential delays that would be caused by the proposed change of site, and show that any such delays are outweighed by the benefit that will be gained from the change of site by the population to be served.

This CON application is for a limited service home health agency. Therefore this criterion does not apply.

NEED

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

The Applicant is a licensed pharmacy serving West Tennessee. This project relates to its current and future operations in that it will enable more rapid hospital discharge and infusion therapy admission for patients who are otherwise ready to go home from the hospital except for availability of skilled infusion nursing services. The limited service home health license will enable Coram to more effectively and expeditiously meet the needs of its infusion therapy patients. On a long term basis, it will enable Coram to better contribute to the adequate and cost effective delivery of healthcare services in West Tennessee.

NEED

4. A. Describe the demographics of the population to be served by this proposal.

The defined service area for Coram's proposed limited service home health agency is 25 counties consolidated throughout West Tennessee. This service area definition was derived from an analysis of the patients currently being served by Coram's Memphis Branch and the geographic designation from which it currently receives its Tennessee patient referrals for infusion therapy products. Patients who are referred from local hospitals to Coram's Memphis Branch who live outside these 25 counties will be referred to Coram's other branches (Knoxville and Nashville) in the state for services.

In the following table is the current (2013) population as estimated by the Tennessee Office of the Governor, forecasted four years from current (2014) to 2018.

Service Area County	Рори	Percent Change	
•	2013	2018	2013-2018
Benton	16,315	16,104	-1.3%
Carroll	28,213	27,831	-1.4%
Chester	17,355	17,999	3.7%
Crockett	14,568	14,683	0.8%
Decatur	11,773	12,080	2.6%
Dyer	38,205	38,427	0.6%
Fayette	40,081	44,888	12.0%
Gibson	50,748	52,163	2.8%
Hardeman	26,492	26,067	-1.6%
Hardin	25,968	26,244	1.1%
Haywood	18,199	18,009	-1.0%
Henderson	28,080	28,631	2.0%
Henry	32,595	32,956	1.1%
Houston	8,358	8,447	1.1%
Lake	9,795	9,468	-3.3%
Lauderdale	27,465	27,125	-1.2%
McNairy	26,408	27,299	3.4%
Madison	99,153	101,001	1.9%
Obion	31,536	31,222	-1.0%
Perry	7,971	8,096	1.6%
Shelby	940,972	954,012	1.4%
Stewart	13,436	13,941	3.8%
Tipton	63,001	67,545	7.2%
Wayne	16,887	16,724	-1.0%
Weakley	38,255	39,491	3.2%
Total	1,631,829	1,660,453	1.8%

Source: Tennessee Department of Health, Office of Policy, Planning and Assessment, Division of Health Statistics, 2014 Revision.

The defined service area currently has 1.632 million persons which are estimated to increase by 1.8 percent to 1.66 million between 2013 and 2018. This is lower than the 4.7 percent expected statewide. With respect to the under 65 and older population, the primary patient focus of this CON application, the 25-county service area is virtually flat while the State is increasing, as reflected in the table below. Notably, however, the portion of the population under the age of 65 is greater in the service area, currently and five years into the future.

Demographic Data	25 County Service Area	State of TN
Total 2013 Population	1,631,829	6,528,014
Total Population, 2018	1,660,453	6,833,509
Total 2018 Population Change (5 Year)	28,624	305,495
Under 65 Population, 2013	1,413,719	5,577,837
Under 65 Population, 2018	1,407,623	5,731,096
Under 65 Population Change (5 Year)	-6,096	153,259
Under 65 Population % of Total Population, 2013	86.6%	85.4%
Under 65 Population % of Total Population, 2018	84.8%	83.9%
Median Household Income, 2014	\$41,684	\$43,390
TennCare Enrollees, 2014 (as of Jan)	372,094	1,190,766
TennCare Enrollees as a % of Total Population, 2013	22.8%	18.2%
Persons Below Poverty Level, 2013 estimate	330,972	1,135,205
% of Total Population Below Poverty Level	20.3%	17.4%

Sources: Population from Tennessee Department of Health, Tennessee Counties and the State; TennCare Enrollees from TennCare latest published data (May 2013); Median Household Income from Claritas, Inc.; and, Percent Poverty Level from U.S. Government as of December 2013 and applied to Tennessee projections of population.

Also presented in the above table is economic information of the service area contrasted with the State. Within the service area, median household income is less than the statewide equivalent, the portion of population below the poverty level is about 16 percent higher and the portion of TennCare enrollees is about 25 percent higher. This indicates a less favorable economic environment in West Tennessee than the State overall, providing more compelling information to establish cost effective healthcare delivery systems providing care in less intense environments such as the home.

These demographic and economic factors demonstrate a need for affordable healthcare and demand a decrease in costs in healthcare delivery. This application is responsive in that it is based on the demonstrated needs of the existing population for whom Coram has identified a gap in service and an access problem related to infusion nursing visits in the home. Coram's patients are quantified within the existing population (demographic and economic factors) of the counties identified above; the identified problem will only be exacerbated without the approval of this CON application.

While traditional Medicare certified home health agencies primarily service the elderly, this will not be the case with Coram's services as proposed via this CON application. In fact, analysis of the Coram Memphis Branch infusion patients, who will become its skilled nursing patients, for the past three years indicate the following age dispersion:

Age Group	Q1-2013	Q2-2013	Q3-2013	Q4-2013	CY 2013
<1 Yr	7	10	6	11	34
1 to 16	13	8	9	11	41
17 to 29	21	16	13	18	68
30 to 49	50	53	41	43	187
50 to 64	74	70	79	50	273
65 to 74	25	37	43	34	139
75 and Older	17	15	14	25	71
Total	207	209	205	192	813
Percent Under Age 65	79.7%	75.1%	72.2%	69.3%	74.2%
Percent 65 and Older	20.3%	24.9%	27.8%	30.7%	25.8%

Source: Corameters Management Report, Memphis Branch, 2/19/2014

In contrast with the average Medicare certified home health agency, actual age dispersion of patients in West Tennessee obtained from the 2013 Joint Annual Report Summary indicates that in the 25 county Service Area, 68 percent of patients are older than age 65 (versus 25.8 percent above). More dramatic is the age distribution of the elderly. Service Area wide, the 75 and older home health services population accounts for 47 percent of all patients. In contrast, only about 9 percent of Coram's patients in its Memphis Branch are 75 years of age or older. In essence, just one in twelve Coram patients is 75+ versus one in two at a typical home health agency.

The patient to be served by Coram's home health infusion nursing service will be primarily under the age of 65. Furthermore, these patients will be either privately insured, self pay or uncompensated. In fact, it is not Coram's intent to obtain Medicare certification for its home health services. Rather it will rely on the available Medicare home health agencies in West Tennessee to meet that client's needs, unless otherwise requested. To demonstrate the difference in patient population, actual visits by payor was obtained from the 2013 Joint Annual Report Summary. This indicates that within the West Tennessee service area nearly 80 percent of the home health agency visits were for Medicare and Medicare HMO clients. And Medicare/Medicare HMO combined with TennCare totals approximately 85 percent of visits. This will contrast with the service proposed via this CON application which will provide no Medicare or TennCare home health visits.

The service proposed to be provided by Coram is strictly limited to skilled nursing visits and specifically infusion related. Again, in analyzing the existing licensed home health agencies in West Tennessee, fifty six percent of those agencies' visits were not skilled nursing visits; just 44 percent were skilled nursing visits. Breakdown by type of skilled visits is not available. However, based on the Applicant's identification of difficulty

accessing home infusion nursing support, it is likely that infusion nursing only comprises a very very small portion of the 44 percent skilled visits. In contrast to available home health agencies, Coram will be different. It will be 100 percent skilled and of the skilled it will be 100 percent infusion nursing and related services.

As demonstrated above, the age profile, payor profile and needs of the Coram infusion nursing patient will differ dramatically from the patient served by the existing home health agencies within the 25 county service area and Statewide.

NEED

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

The population to be served by Coram via this CON application is unique in contrast to other home health agencies. The patient profile is derived from Coram's existing patient profile as those are the persons who will receive infusion nursing services in the home. As noted previously, Coram estimates approximately 22 percent of its ongoing census will have a need for infusion nursing services provided by Coram. These patients are specialized with special needs. They include patients with compromised immune system or auto immune disorders, transplant patients, congestive heart failure patients, patients who cannot consume nutrition or food via regular intake, hemophiliacs or patients with other blood clotting disorders, patients with progressive emphysema, among others.

The specialized needs of these patients can be met via Coram's provision of infusion therapy products in the home, supported by Coram's proposed infusion nursing services which will include patient/family education for self administration. Benefits of home infusion depending on the patient include, but are not limited to, the following:

- > Earlier hospital discharge, or hospital avoidance
- Positive outcomes
- > Multiple drug therapies managed by experience clinicians in the home
- > First dosing protocols in the home
- > PICC line and IV access management
- > Trended lab results
- > Therapeutic drug monitoring and pharmacokinetic drug dosing
- > Education materials which include pictures and written step by step instructions
- > Personalized training by nurse clinicians
- > Nursing visits to reassess techniques and reinforcement training as needed
- > 24-hour access to Coram clinicians
- > Patient service representative to act as the patient's liaison

Relative to the patient profile, Coram expects that five percent of its patients will be medically indigent with Coram providing the nursing service free of charge (charity care), other persons will not be able to afford their treatment but not considered charity care and the balance covered by either self pay or third party payor. The majority of the patients will be under the age of 65, many of whom are still working and therefore can not afford to not receive in home services and self administration education.

NEED

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

Coram Alternate Site Services, Inc. proposes to become a restricted license home health service, and under this license only provide infusion nursing and related services in the patient home. This is unique in contrast with the Medicare certified home health agencies available in West Tennessee. Uniqueness is attributable to the following factors: (1) restricted license to only provide infusion nursing and related services; (2) not Medicare or Medicaid certified; (3) patients primarily under the age of 65; (4) patient may not be home bound but the service is more appropriate in the home (due to cost, compromised immune system, accessibility, education/training, etc.); (5) without availability of Coram's services, many patients remain in the hospital unnecessarily; (6) Coram's certified nurse infusion professionals; (7) Coram's education and training of Medicare certified agencies to assume the patient population when appropriate; (8) Coram's first dose policy/protocol; among others.

While this proposal is unique and therefore not directly competitive with existing licensed home agencies in the Service Area, in accordance with information requested in this question, the following table provides the names and utilization (visits) for home health agencies listed in the Joint Annual Report Summary as being existent in one of the 25 counties defined as the Coram Alternate Site Services Service Area:

Licensed Agency	County	2011	2012	2013	# of Svc Area
					Counties
Professional Case Management of TN	Anderson	0	1	0	0
Tennessee Quality Homecare – NW	Benton	824	837	824	8
Baptist Memorial Home Care & Hospice	Carroll	235	213	260	8
Alere Women's and Children's Health	Davidson	1	1	1	1
Amedisys Home Hith (Cumberland Bend)	Davidson	78	79	114	2
Elk Valley Health Services Inc	Davidson	47	50	74	19
Home Care Solutions, Inc	Davidson	29	18	7	1
Willowbrook Home Health Care Agency	Davidson	1	1	1	1
Tennessee Quality Homecare – SW	Decatur	1,195	964	912	8
Volunteer Homecare of West Tennessee	Decatur	1,299	1,260	1,313	9
Regional Home Care, Dyersburg	Dyer	744	814	707	6
NHC Homecare	Fayette	254	216	579	7
Where The Heart Is	Fayette	253	285	116	3
Amedisys Home Care (NHC in 2010)	Gibson	479	625	569	12
Volunteer Home Care, Inc	Gibson	2,486	2,975	3,000	12
Deaconess Homecare II	Hardin	1,117	1,153	1,216	9

Licensed Agency	County	2011	2012	2013	# of Svc Area Counties
HMC Home Health (Extendicare 2010)	Hardin	252	274	341	5
Regional Home Care – Lexington	Henderson	678	616	569	8
Henry County Medical Center Home HIth	Henry	354	401	363	5
Hickman Community Home Care, Inc	Hickman	2	0	3	1
Amedisys Home Health Care	Madison	2,489	2,586	2,741	18
Extendicare Home Health of West TN	Madison	962	993	0	0
Intrepid USA Healthcare Services	Madison	294	86	422	15
Lifeline of West Tennessee	Madison	0	0	1,085	20
Medical Center Home Health	Madison	1,403	1,617	1,706	14
Regional Home Care, Jackson	Madison	1,206	1,061	1,159	14
Careall Homecare Services	Maury	16	16	104	4
Maury Regional Home Services	Maury	4	4	1	1
NHC Homecare	Maury	31	22	50	4
Gateway Home Health Clarksville	Montgomery	84	176	82	2
Suncrest Home Health of Nashville, Inc.	Montgomery	53	32	42	2
Extendicare Home Health of Western TN	Obion	398	347	81	3
Amedisys	Overton	0	0	221	1
Highland Rim Home Health Agency	Putnam	0	0	4	1
NHC Homecare	Rutherford	0	0	88	1
71174714111	Shelby	9	14	12	1
Accredo Health Group Alere Women's & Children's HIth	Shelby	357	370	373	7
	Shelby	882	938	1,061	3
Amediays Home Care	Shelby	2,411	1,806	1,933	3
Amedisys Home Health	Shelby	576	683	936	3
Amedisys Home Health Care			1,727	1,811	2
Americare Home Health Agency	Shelby Shelby	1,324 3,248	3,367	3,862	3
Baptist Trinity Home care		1	3,307	0	0
Baptist Trinity Home care - Private Pay	Shelby	311	366	364	1
Best Nurses	Shelby		341	79	1
Elder Care	Shelby	780	863		1
Family Home Health Agency	Shelby	375		379	3
Functional Independence Home Care	Shelby	725	804	953	
Home Health Care of West Tennessee	Shelby	1,308	1,118	1,010	4
Homechoice Health Services	Shelby	2,037	1,164	861	6
Interim Healthcare of Memphis	Shelby	720	889	769	3
Intrepid USA Healthcare Services	Shelby	662	615	603	3
Maxim Healthcare Services	Shelby	103	197	155	6
Methodist Alliance Home Care	Shelby	2,958	2,939	2,935	3
No Place Like Home	Shelby	38	55	58	3
Senior Services Home Health	Shelby	642	697	609	1
Still Waters Home Health Agency	Shelby	105	127	101	1
Willowbrook Visiting Nurse Association	Shelby	473	533	479	5
Baptist Home Care/Hospice - Covington	Tipton	326	361	355	6
Prof'l Home Hith Care (CareAll 2010)	Tipton	1,491	1,103	1,305	12
Careall Homecare Svcs/Univ. Home HIth	Weakley	1,755	2,440	1,897	11
Guardian Home Care of Nashville, LLC	Williamson	44	47	49	2
Vanderbilt HC Affiliated w/ Walgreens IV	Williamson	0	0	3	2
Careall	Wilson	2	0	0	0
Magnolia Regl Hlth Ctr HH & Hospice	Out of State	39	53	43	2
Regional Home Care Parkway	Out of State	31	14	28	1
Total		41,001	41,356	41,778	

Source: Joint Annual Report of Home Health Agencies, Attachment C, pages 6 through 10. Patients Serviced for the Service Area Counties per the Joint Annual Report Summary as reported in Report #6. The Number of Service Area Counties represent those counties within the Coram West Tennessee Service Area in which each home health agency had patients during 2013.

As noted, while these agencies are listed, their patients are 85 percent Medicare/Medicare HMO/TennCare, which Coram will not serve. They are 56 percent non-skilled or therapy visits, which Coram will not serve. They are 44 percent skilled visits of which only a small fraction if any at all are infusion type patients. Furthermore, as the Service Area Study indicates, area home health agencies do not generally provide first dose therapies, IVIG or Alpha1 therapies.

NEED

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

Following is the most recent three year infusion therapy product activity for the Applicant's Memphis Branch licensed pharmacy:

Factor	CY 2011	CY 2012	CY 2013
Infusion Therapy Patients	1,043	966	820
Infusion Therapy Patient Months	1,948	1,804	1,532

The above patients represent the number of patients who received infusion products from Coram's Memphis Branch (licensed pharmacy) during the past three calendar years. The average length of stay (therapy product duration) of the infusion patients is approximately two months.

In the following table is the two forecasted years for the infusion product patients following completion of the project, which will be two years beginning January 2015. The infusion nursing patients to be treated by the home health agency upon licensure are a subset of the infusion therapy patients budgeted for the next two years in this table. The forecasted skilled nursing patients and visits and the supporting methodology follow the table.

	Before Project	After Project Completion		
Factor	2013	Year One	Year Two	
Infusion Therapy Patients	820	911	1,002	
Infusion Therapy Patient Months	1,532	1,804	1,984	

To estimate the number of infusion nursing patients and their related skilled visits for the forecast period, the Applicant considered the types of infusion therapy products which comprise the patient therapies and the average monthly census in the above table as well as the hardship the Applicant has encountered in various situations throughout West Tennessee in obtaining qualified infusion nursing services from other third parties. This affected the analysis because Coram is not intending on competing with existing available services but rather responding to a community need based on the gap in service which equates to a lack of availability or accessibility of infusion nursing services.

As noted previously, there are primary differences between two types of Coram patients. One is the more typical infusion therapy patient receiving antibiotics, TPN, pain management, cardiac and the like; the other is the specialty patient receiving

immunoglobin or alpha 1 therapies. The former therapies comprise 84 percent of Coram's services; the specialty patients comprise 16 percent of the therapies provided. In terms of estimated requirement for infusion nursing services, it is estimated that 100 percent of the specialty patients will require the service. The reason for such high utilization is these patient infusions last up to 6 hours per treatment and/or are not homebound. As such, the more traditional home health agency providing intermittent services is not generally staffed for nor compensated for under Medicare guidelines such long nursing visits.

Ongoing, Coram has significant challenges to find nursing services for these patients resulting in these patients remaining in the hospital for an unnecessary prolonged period, having the patient travel to his/her physician office for Coram to meet the patient in that setting or having the patient travel to another licensed location – all creating hardship on the patient and family.

For the balance of Coram's therapy patients, it is estimated that just 5 percent of those patients will require infusion nursing provided by Coram's home health agency. Similarly, this patient estimate is based on the Applicant's assessment of its patient case load and the challenges it regularly faces in admitting a patient to the pharmacy service that can not obtain at home support to initiate the infusion therapy. Depending on the therapy, each patient will receive between two and four visits per month.

Extrapolating the above utilization assumptions and applying them to the estimated monthly census of infusion therapy patients results in a computed approximate 22 percent of Coram's pharmacy patients requiring skilled nursing services be provided by Coram. In the following table are the total number of home health patients and visits for each of the first two forecast years:

Factor	Year One	Year Two
Number of Home Health Patients	207	228
Chilled Have Harlib Visite had C.		
Skilled Home Health Visits by Infusion Therapy	Type	
Aralast Alpha-Proteinase Inhibitor	300	330
Immunoglobulin IV	277	305
Immunoglobulin Subcutaneous	150	165
Investigational Drug	66	73
Zemaira Alpha Proteinase Inhibitor	400	440
Other Specialty	31	33
Subtotal	1,224	1,346
All Other (TPN, Antibiotics, Etc)	551	606
Total Annual Skilled Nursing Visits	1,775	1,952

As noted in the above table, the forecasted patients in years one and two are 207 and 228, respectively. Visits total 1,775 in year one and 1,952 in year two. This results in an average of approximately eight visits per patient. This is yet another differentiating factor between the Medicare certified home health agency and the Coram proposed restricted service agency.

ECONOMIC FEASIBILITY

- 1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.
 - All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
 - The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
 - The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
 - For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.

The Project Cost Chart is provided on the following page. Assumptions supporting each of the line items immediately follow the chart.

74R

PROJECT COST CHART

P	\ Co	nstruction and equipment	acquired by purchase:		
	1	Architectural and Engin	eering Fees		\$0
	2	Legal, Administrative (E	excluding CON Fee), Consultants Fee		\$88,000
	3	Acquisition of Site			\$0
	4	Preparation of Site			\$0
	5	Construction Costs			\$0
	6	Contingency Fund			\$0
	7	Fixed Equipment (not in	Construction Contract)		\$0
	8	Moveable Equipment (L	ist all equipment over \$50,000)		\$0
	9	Other	A THE LOCAL PROPERTY OF THE PARTY.	d.	\$0
В	Cor	nstruction and equipment	acquisition by donation or lease		
	1	Facility (inclusive of land	l and building)		\$0
	2	Building Only			1 1 3 6 5 5 4 5 4 5 50
	3	Land Only			\$0
	4	Equipment (Specify)			\$0
	5	Other (Specify)	Prorated Allocation of Five Year Lease		\$7,000
С	Fina	ancing Costs and Fees			
	1	Interim Financing			\$0
	2	Underwriting Costs			\$0
	3	Reserve of One Year's D	Pebt Service		\$0
	4	Other (Specify)	12.45 E35 - 1.125 - 1.		\$0
D	Estir	mated Project Cost (A+B+	C)		\$95,000
Ε	CON	I Filing Fee			\$3,000
F	Tota	l Estimated Project Cost (D+E)	TOTAL	\$98,000

Project Cost Chart, Underlying Assumptions

The underlying assumptions for the Project Cost Chart on the preceding pages are summarized in the following paragraphs.

- > Line A 1, Architectural and Engineering Fees: Not applicable as there is no design and construction involved in this project.
- ➤ Line A 2, Legal, Administrative, Consultants Fee: These costs represent legal, administrative and consulting associated with preparing and filing the CON application including a contingency for such costs and the home health license application fee of \$1,080. There are no pre-opening costs as the existing operations have the infrastructure necessary to add the limited home health services without the additional of any support personnel or additional physical space.
- ➤ Line A 3, Acquisition of Site: Not applicable as the service will be incorporated into the existing leased space at 1680 Century Center Parkway, Suite 12, Memphis, TN 38134.
- > Line A 4, Preparation of Site: Not applicable as there is no design and construction involved in this project.
- ➤ Line A 5, Construction Costs: Not applicable as there is no design and construction involved in this project.
- ➤ Line A 6, Contingency: Not applicable as there is no design and construction involved in this project.
- > Line A 7, Fixed Equipment: Not applicable as there is no design and construction involved in this project.
- ➤ Line A 8, Moveable Equipment: Not applicable as there is no addition of infrastructure to house the nurses and the infusion equipment is already owned by Coram and housed at its offices.
- > Line A 9, Other: Not Applicable.
- ➤ Line B 1 through 5: Line 5 includes a prorated allocation of the home health's percent of the overall leased space, based on a five year agreement.
- ➤ Line C 1 through 4: This is not applicable as the costs of implementing the program are being funded from cash reserves.
- ➤ Line D: This is the subtotal of A, B and C above.
- > Line E: This is the applicable CON application fee payable to the State of Tennessee.
- ➤ Line F: This is total project costs.

PAGE 75R

ECONOMIC FEASIBILITY

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)

- A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
- D. Grants--Notification of intent form for grant application or notice of grant award; or
- E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- F. Other—Identify and document funding from all other sources.

The project proposed by the Applicant will be funded from cash reserves. As demonstrated in the Historical Data Chart, the Applicant generates more than sufficient Net Operating Income to fund the minimal costs associated with establishing the limited service home health agency. Additionally, Michael E. Dell, Senior Vice President, General Counsel and Secretary, has provided a letter indicating the project will be funded from cash reserves. This is provided in Attachment, Section C, Economic Feasibility, Item 2. Included within Attachment, Section A, Item 4.2 is the Applicant's ultimate parent's audited financial statements which clearly demonstrate adequate funding available for the project as proposed.

ECONOMIC FEASIBILITY

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

The project costs for the proposed limited service home health agency are restricted to Line A 2, legal, administrative and consulting fees and Line E, the CON application fee. The existing infrastructure of the licensed pharmacy located at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee will also house the home health agency. There is no construction, renovation, expansion or additional resources required to add this service as the space is fully functioning and has the management and support personnel to assume responsibility for the home health agency services.

Administrative, legal and consulting fees are based on costs incurred to prepare the CON application, anticipated costs to be incurred up through the HSDA hearing on this matter and the home health licensing fee, along with some contingency. The CON application fee is based on the minimum filing fee established by the HSDA of \$3,000. Combined, total project costs are \$98,000.

ECONOMIC FEASIBILITY

4. Complete Historical and Projected Data Charts on the following two pages – <u>Do not modify the Charts provided or submit Chart substitutions!</u> Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the Proposal Only (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

The Historical Data Chart for the Existing Operation of Coram Alternate Site Services, Inc. is included on the following page. The three most recent years of operation are calendar years 2011, 2012 and 2013. This chart presents the existing utilization and financial information for the licensed pharmacy operation discussed herein as the Memphis Branch.

The Historical Data Chart is for the pre-existing infusion pharmacy business only. All pharmacy revenues are booked at the contractual rates with the third party payers, rather than at an arbitrary list price with a contractual adjustment to the amount to contract. Accordingly, there are no contractual allowances shown in the Historical Data Chart for the existing infusion pharmacy business, nor in any future budgets for the existing infusion pharmacy business. As shown on the Historical Data Chart, the Memphis Branch generates positive net income sufficient to support the implementation of the home health service proposed via this CON application.

Following the Historical Data Chart is the Projected Data Chart. This chart provides the utilization and financial information for the first two years of operation of the home health agency service. As instructed, the Projected Data Chart included herein on page 82 presents only the proposed new service — the limited service home health agency. Immediately following the Projected Data Chart is a list of the assumptions supporting the projection.

The Projected Data Chart on page 82 of the application ONLY considers the projected infusion therapy home health agency volume. The gross charges are listed at an average of \$150 per visit based on mix of short and long duration visits; average reimbursement is expected to be \$133. Accordingly the \$17 differential in this calculation is reflected as a contractual allowance from third party payers, charity care and bad debt. This is for those payers other than Medicare or TennCare since the Applicant will not be participating or making claims to either of those payors for infusion home health services.

We also note that within Attachment, Section C, Economic Feasibility, Item 4 of this CON application, the Applicant included Projected Data Charts for the infusion pharmacy by itself and Projected Data Charts that consolidate the projections for the infusion pharmacy business line together with the projections for the infusion home health services line which shows contractual allowances for home health services but none for pharmaceutical, which, as noted above, is consistent with the Applicant's historical experience.

HISTORICAL DATA CHART - EXISTING MEMPHIS OPERATIONS

Give information for the last three (3) years for which complete data are available for the facility or agency. The fiscal year begins in: (month)

•••	, ,,,,,	(HIOHIII)			
Yea	аг		2011	2012	2013
Α	Util	zation Data Patients Infusion Patients Infusion Pt Months Nursing Visits Home Health RN Visits	1,043 1,948 0	966 1,804 0	820 1,532 0
В		renue from Services to Patients Inpatient Services			
	2	Outpatient Services	\$6,016,665	\$5,619,668	\$5,392,631
	3	Emergency Services			
	4	Other Operating Revenue	化对方可证	ENTATES	
		ss Operating Revenue	\$6,016,665	\$5,619,668	\$5,392,631
С	Ded 1	uctions from Gross Operating Revenue Contractual Adjustments			n ku elon
	2	Provsion for Charity Care	\$59,571	\$55,640	\$53,392
	3	Provisions for Bad Debt	\$112,656	\$221,269	\$67,216
	Tota	I Deductions	\$172,227	\$276,909	\$120,608
NET	OP	ERATING REVENUE	\$5,844,438	\$5,342,759	\$5,272,023
D	Ope 1 2	rating Expenses Salaries and Wages Benefits Physician Salaries and Wages	\$1,344,288 \$158,361 \$0	\$1,483,539 \$179,422 \$0	\$1,374,241 \$162,459 \$0
	3	Supplies	\$24,319	\$29,097	\$25,832
	4	Taxes	\$19,530	\$16,791	\$22,732
	5	Depreciation	\$19,365	\$10,392	\$12,001
	6	Rent	\$79,760	\$94,354	\$105,466
	7	Interest, Other than Capital	\$0	\$0	\$0
	8	Management Fees: a. Fees to Affiliates b. Fees to Non-Affiliates	\$0 \$0	\$0 \$0	\$0 \$0
	9	Other Expenses - Specify on Separate Page	\$3,618,344	\$3,282,733	\$3,449,939
٦	Fotal	Operating Expenses	\$5,263,967	\$5,096,328	\$5,152,670
Ε (Othe	Revenue (Expenses - Net (Specify)	i ingar, mayi	COLOR DIFFE	
NET	OPE	RATING INCOME (LOSS)	\$580,471	\$246,431	\$119,363
F (al Expenditures Retirement of Principal		1840-11-5469	
	2	interest			Janes Williams
Т	otal	Capital Expenditures	50	\$0	\$0
NET	OPE	RATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$580,471	\$246,431	\$119,353

HISTORICAL DATA CHART - OTHER EXPENSES

OTHER EXPENSE CATEGORIES Drugs/Materials Shipping/Delivery \$3,353,181 \$3,043,718 \$3,227,553 2 \$85,546 \$84,968 \$70,827 Travel/Lodging Operational Costs: Utilities, Telephone, Professional Fees, and Other Adminstrative Costs \$32,219 \$27,500 \$29,289 4 5 \$147,398 \$126,547 \$122,270 6 Company Caragiva Total Other Expenses

PROJECTED DATA CHART -- NEW BUSINESS LINE

HOME HEALTH/NURSING VISITS - WEST TN (MEMPHIS BRANCH)
Give information for the two (2) years following the completion of this proposal.
The fiscal year begins in: January (month)

Yea	ar		Year One	Year Two
Α	Utili	zation Data Patients Home Health Patients Home Health RN Visits	207	228 1,952
В	Rev	venue from Services to Patients Inpatient Services	380	530
	2	Outpatient Services	\$265/643	\$306702
	3	Emergency Services	\$0	\$0
	4	Other Operating Revenue	\$ 50	50
	Gro	ss Operating Revenue	e 3265,548	S02702
С	Ded 1	uctions from Gross Operating Revenue Contractual Adjustments	\$10,622	\$12,268
	2	Provsion for Charity Care	\$13,277	\$15,335
	3	Provisions for Bad Debt	\$5,311	\$6,134
	Tota	al Deductions	\$29,210	\$33,737
NET	OP	ERATING REVENUE	\$236,333	\$272,965
D	Ope 1 2 3	rating Expenses Salaries and Wages Benefits Physician Salaries and Wages Supplies	\$160,040 \$32,008 \$0	\$181,325 \$36,265 \$0
	4	Taxes	\$0	\$0
	5	Depreciation	\$0	\$0
	6	Rent	\$0	(0)
	7	Interest, Other than Capital	\$0	\$0
	8 P	Management Fees: a. Fees to Affiliates b. Fees to Non-Affiliates Other Expenses Specify in chart	\$0 \$0 \$36,704	\$0 \$0 \$42,951
		Operating Expenses	\$235,851	2 5 5 2 6 8 5 6 5 7)
		r Revenue (Expenses - Net (Specify)		
NET	OPE	ERATING INCOME (LOSS)	\$482	\$4,614
F		tal Expenditures Retirement of Principal	Zang at a same	
	2	Interest	然是这些一种	
	Fotal	Capital Expenditures	\$0	\$\$0
NET	OPE	ERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$482	\$4,614 82

PROJECTED DATA CHART - OTHER EXPENSES

OT	HER EXPENSE CATEGORIES		
1	Drugs/Materials	\$0	\$0
2	Shipping/Delivery	\$0	\$0
3	Travel/Lodging	\$0	\$0
4	Operational Costs: Utilities, Telephone, Professional Fees, and Other Adminstrative Costs	\$0	\$0
5	Mileage	\$36,704	\$42,951
6		·=======	
7			
	Total Other Expenses	\$36,704	\$42,951

Projected Data Chart, Underlying Assumptions

The underlying assumptions for the Projected Data Chart on the preceding page are summarized in the following paragraphs.

- > Utilization: Line A is utilization information based on the analysis presented herein.
- ➤ Gross Revenues: Line B 2 is forecasted outpatient revenues as discussed in responses to the Economic Feasibility questions herein; these charges are based on Coram's self pay charge structure it has established nationally for home health skilled nursing visits and inflated by five percent to represent years one and two dollars.
- Contractual Adjustments: Line C 1 represents deductions from Gross Revenues based on the anticipated contractual rates for services with third party payors and private parties; because gross charges are established herein based on Coram's self pay charge structure inflated to year one, contractual adjustments reflect four percent of gross charges, not including charity care and bad debt.
- Provisions for Charity Care: Line C 2 represents anticipated charity care which equates to five percent of net patient revenues (Gross Revenues less Contractual Adjustments).
- Provisions for Bad Debt: Line C 3 represents anticipated bad debt which equates to two percent of net patient revenues (Gross Revenues less Contractual Adjustments).
- Operating Expense: Line D 1 represents salaries per the staffing schedule provided in response to Section C, Orderly Development of Health Care, Question 3. This is strictly registered nurse personnel for the new program as incremental staff. It is expected that there will be one full time employee and the balance of the nurse requirements will be provided by Coram's pool nurses on an hourly basis. Line D 2 represents the estimated benefits for the full time registered nurse at 20 percent of the respective salary. While the pool/per diem nurses do not receive benefits, the 20 percent factor is included in the salary line item to accommodate any potential increase for hourly services. Line D 3 is the supply line item, estimated at \$4 per visit. Line D 9 represents mileage reimbursement assuming an average mileage reimbursement of 47 miles per visit at 44 cents reimbursement per mile. Regarding taxes, the Applicant's financial performance is rolled up into the company financials. At the branch level, it pays no federal taxes or excise taxes at this time. Regarding franchise taxes, those are included for the branch overall in the existing business chart. As a result of operating the home health agency in the existing pharmacy. the Applicant does not anticipate any material taxes payable yet proportionately has added taxes consistent with what it currently pays for the existing operation.
- > Net Operating Income: Both years reflect a positive net operating income which demonstrates this project is financially feasible.

ECONOMIC FEASIBILITY

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

The following table provides the average gross charge derived from the Applicant's self pay charge structure it uses nationally for home health skilled nursing visits in 2014, inflated five percent to represent year one dollars, average deduction from third parties, charity deductions and bad debt deductions. The result is net revenue for each of the two forecasted years of operation. Also included is number of visits and resulting average net revenue per visit:

Projected Data Chart	Year One	Year Two
Gross Charges	\$265,543	\$306,702
Deductions	(\$10,622)	(\$12,268)
Charity	(\$13,277)	(\$15,335)
Bad Debt	(\$5,311)	(\$6,134)
Net Revenue	\$236,333	\$272,965
		1
Patients	207	228
Visits	1,775	1,952
Average Gross Charge/Visit	\$150	\$157
Average Gross Charge/Visit Average Gross Charge/Patient	\$1,281	\$1,345
Deductions/Patient	\$141	\$148
Average Net Revenue / Patient	\$1,140	\$1,197
Average Net Revenue / Visit	\$133	\$140

These average net revenue amounts per visit represent a blend of the average type patient with up to two hours per visit and the specialty patients who have visits lasting up to six hours.

ECONOMIC FEASIBILITY

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Since this is a new service for the Applicant in West Tennessee and the defined service area, there are no existing or current charges for skilled nursing visits. The proposed charges for skilled nursing visits are based on Coram's experience in other jurisdictions in which it provides home health services, including Nashville, and in particular its self pay charge structure. The average charge per visit is \$150 in year one and \$157 in year two. Given the expected duration of the nursing visits by Coram, and three times the requirement for the specialty infusion type patients, this is reasonable. Accordingly, the average charge per visit for an antibiotic or TPN type patient is \$116; the average charge for the specialty IVIG and alpha 1 patient is \$290 to 348 per visit

Net revenue per visit for the typical antibiotic or TPN type patient is estimated to be \$104 per visit. The specialty type patient which requires two and one half to three times the initiative is estimated at \$250 to \$310 per visit. These amounts are inflated between years one and two for inflationary purposes.

ECONOMIC FEASIBILITY

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

The proposed average charge per home health visit for year one is \$116 for up to a two hour visit. For longer visits, there is a \$58 charge for each additional hour. This results in the typical infusion patient at \$116 per visit and three times that amount, or \$290 to \$348, for the specialty infusion patient whose treatment lasts approximately six hours.

To contrast these charges to home health agencies in the service area, it is more reasonable to contrast the typical rate, excluding the specialty rate based on the fact that Medicare certified home health agencies do not generally provide the specialty infusion nursing. Within the 2013 Joint Annual Report Summary is reported charge per visit by home health agencies by discipline. Of the 61 agencies reporting from within the defined service area for 2013, only 8 reported an average charge for a skilled nursing visit. These charges ranged between \$81 and \$155 per visit.

Following are the eight agencies by name and charge per skilled visit as reported in their 2013 Joint Annual Report.

Agency Name	2013 Charge Per Skilled Visit
Tennessee Quality Homecare - Northwest (Benton)	\$90
Tennessee Quality Homecare - Southwest (Decatur)	\$90
Volunteer Homecare of West TN, Inc. (Decatur)	\$120
Volunteer Home Care, Inc. (Gibson)	\$120
Acredo Health Group (Shelby)	\$90
Baptist Trinity Home Care - Private Pay (Shelby)	\$155
Interim Healthcare of Memphis, Inc. (Shelby)	\$95
Maxim Healthcare Services, Inc. (Shelby)	\$81

Source: Report 3 from the 2013 Joint Annual Report Summary.

Adjusting the range from 2013 dollars to 2015 dollars would result in a 2015 dollar range of \$89 to \$171 charge per visit. Comparing this charge to the typical charge per visit identified above, the Applicant's charges are within the range of reasonableness.

ECONOMIC FEASIBILITY

7. Discuss how projected utilization rates will be sufficient to maintain costeffectiveness.

Forecasted visits for years one and two for the Coram home health agency demonstrate that the proposed program is financial viable. Because the existing infrastructure of the pharmacy, its physical space, its management team and its support staff are all in place, the incremental costs associated with the home health agency directly relate to the nurse staff to provide the skilled visits with respect to their compensation and benefits and travel reimbursement.

All infusion products and necessary equipment are provided through the licensed pharmacy in conjunction with the prescribed infusion therapies.

Therefore, this proposed home health agency is very cost effective, with the nurse staff being added as volumes increase.

As is evidenced on the Projected Data Chart, the home health program demonstrates positive net operating income and therefore demonstrates its viability.

ECONOMIC FEASIBILITY

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Forecasted utilization in year one results in positive net operating income; forecasted utilization in year two results in greater positive net operating income. Given the fact that all of the incremental costs associated with the home health operation are variable relative to the number of skilled nursing visits, and the average cost per visit is less than the net revenue realized per visit, the Applicant can assure the financial viability of this proposal.

With respect to sufficient cash flow until financial viability is achieved, given the cost variability of this business, there will be sufficient cash flow to cover operating costs. Notwithstanding this fact, a letter from the Applicant's ultimate parent included in Attachment, Section C, Economic Feasibility, Item 2 indicates that the ultimate parent will not only fund the initial project costs, it will provide for any necessary working capital and operating deficits, if any, until financial viability is achieved.

ECONOMIC FEASIBILITY

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

The Coram Memphis Branch licensed pharmacy participates in both Medicare and TennCare and also serves medically indigent patients. The home health agency proposed by this CON application will not become Medicare/Medicaid certified. Because it is a limited service home health agency, and not providing the full range of home health services as prescribed by the Conditions of Participation, it is not eligible for certification.

Its patients will be private pay, covered by a third party provider and medically indigent. Per the Projected Data Chart, approximately five percent of the patients are expected to be charity care.

ECONOMIC FEASIBILITY

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alphanumeric order and labeled as Attachment C, Economic Feasibility-10.

Coram Alternate Site Services, Inc. is a wholly owned indirect subsidiary of CVS Caremark Corporation. Currently Coram Alternate Site Services, Inc. is not separately audited as it operates as a division of its ultimate parent, CVS Caremark Corporation. The ultimate parent's annual report as filed with the Securities and Exchange Commission which includes audited financial statements for the company is provided as Attachment, Section A, Item 4.2. The local branch financial statements are provided as Attachment, Section A, Item 4.4.

The audited financial statements as presented in the CVS 10K indicates, the ultimate parent has in excess of \$4.0 billion in cash and cash equivalents, \$25 billion in current assets and just \$12.8 billion in long term debt. Its current ratio is 1.64 showing good financial strength. The local branch financial statements indicate positive earnings for each of the last three years.

With this project being a low cost project (\$98,000) and the net operating income provided by the Memphis Branch's licensed pharmacy (without the project), the Applicant clearly has the financial capability to implement and operate the proposed home health agency. Additionally, the Applicant has provided a Funding Letter assuring this fact by Michael E. Dell, Senior Vice President, General Counsel and Secretary. This is included in Attachment, Section C, Economic Feasibility, Item 2.

ECONOMIC FEASIBILITY

- 11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:
 - a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

The benefits intended by this proposal are varied for the patient/family, the physician and hospital referral source and the home health industry.

Patients/families will have more timely discharges from the hospital and be able to receive first dose protocols, teaching/training in self administration and readily accessible infusion in their own home. There is no less costly or more effective alternative for the patient and family.

With respect to the hospital and physician referral sources, as documented in this CON application, if a hospital inpatient prescribed infusion therapy services is unable to obtain home health assistance upon hospital discharge that individual remains in the hospital until s/he receives the first infusion and training sufficient that s/he could be discharged home to self-infuse thereafter. Subsequently, the Applicant would send the compounded infusion product from the Memphis pharmacy via secure medical courier. If the infusion therapy is inappropriate to administer in the home without nursing supervision, such as blood products or IVIG, the patient must travel to an outpatient clinic, such as an oncology clinic, physician practice, hospital or ambulatory infusion suite to obtain their medication. In addition, patients without nursing assistance who self-infuse in the home are ill equipped to handle even the most minor of complications, such as a blocked line, and must instead travel to the nearest hospital emergency room, sometimes by private transportation, but also by ambulance, to alleviate the problem. Similarly, patients who require a line change must also go to a hospital for such a procedure.

The lack of availability of home health agencies to provide first dose protocol, meet the needs of low intervention patients (not homebound), be available to start a patient on the evening, night or weekend therapy regimen or provide extended IVIG nursing visits is well documented. The result is the patient remains in a hospital longer than necessary resulting in an increased cost to the healthcare system. All of these situations, and their attendant expenses, would be substantially eliminated by the Applicant implementing its limited service home health agency. Accordingly, approval of Coram to provide this limited home health service will clearly result in a less costly and more effective alternative with respect to the hospital and other referral sources.

With respect to licensed home health agencies throughout West Tennessee, unfortunately in today's Medicare home health agency environment, there is not a range of certified infusion nurses available at the existing home health agencies. This is a very small skilled niche primarily providing services to non-Medicare patients. Accordingly, the service proposed herein is atypical to the average home health agency and generally not available. A detailed discussion of home health agencies patients versus the patient to be seen by the Coram home health service is presented by the Applicant in response to questions within Section C, Need, Home Health Services.

The alternative to this proposal is maintaining status quo. This was rejected by the Applicant. Maintaining status quo in West Tennessee means continued longer stays in hospitals; more costly hospital stays; further hardships on patients and their families; inability to enhance quality of infusion therapy services in West Tennessee; operating in a more costly healthcare environment — despite the industry's focus on enhancing quality and decreasing costs; and rejecting a true improvement in healthcare delivery at a lesser cost.

ECONOMIC FEASIBILITY

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

The project proposed herein is for a limited service home health agency. It does not involve any new construction. In fact, it is using its existing infrastructure that houses a licensed pharmacy to establish the home health agency. Therefore the physical plant exists, is fully built out, and will require no incremental costs by the Applicant to achieve licensure of the home health service.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

The Applicant is an existing licensed pharmacy. It currently has in place contractual agreements with managed care organizations throughout West Tennessee. These include but are not limited to the following Aetna, Blue Cross Blue Shield of Tennessee, Carecentrix, Cigna, Corizon, Coventry, Cover Tennessee, GEHA, Multiplan, HealthSprings of Tennessee, Magellan TennCare, Prime Healthcare, Medicare, St Jude and TriCare.

Aside from its payor relationships, the Applicant has significant referral relationships with the existing hospital and provider community throughout the 25-county defined service area. The provider relationships include but are not limited to the following: St. Jude Children's Hospital, St. Francis Hospital, Vanderbilt University Medical Center, Methodist University Hospital, Methodist Germantown, Le Bonheur Children's Medical Center, Baptist Memorial – DeSoto, Baptist Memorial Hospital, Methodist North Hospital, Regional Medical Center, Select Specialty, and VA Medical Center. Collectively, these referral sources represent between 80 and 90 percent of the Applicant's patient referrals.

The Applicant will extend the above payor relationships and provider relationships to also include nursing services for infusion patients. As evidenced by the letters of support obtained by the Applicant for this CON application, it is clear Coram has the necessary existing resources to assure its future viability.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

This proposal will not negatively impact existing home health providers as the services proposed herein will be very restricted and complement the home health services provided by agencies throughout West Tennessee. Additionally, with Coram's intent to continue to train nurses at other home health agencies in the area of infusion, it is possible the quality of care in the overall home health community will increase. Importantly, Coram only anticipates admitting approximately 200 of more than 40,000 home health patients in the region demonstrating virtually no impact on existing providers.

Coram's restricted license will have quite a positive effect on the existing institutional and physician providers. As noted in Section C, Question 1, Coram has a referral relationship for its infusion products with hospitals such as St. Jude Children's Hospital, St. Francis Hospital, Vanderbilt University Medical Center, Methodist University Hospital, Methodist Germantown, Le Bonheur Children's Medical Center, Baptist Memorial – DeSoto, Baptist Memorial Hospital, Methodist North Hospital, Regional Medical Center, Select Specialty, and VA Medical Center, among others. With the ability to have Coram's certified infusion nurses available for first dose protocol and training in a patient's home, patients will be discharged on a more timely basis from these and other area hospitals. The ultimate effect will be a decrease in patient care costs across the continuum of the healthcare system.

Other benefits Coram believes will accrue to the community at large with its ability to provide infusion nursing services include but are not limited to the following:

- Less emergency room use
- Better disease control
- > Fewer unscheduled physician office visits
- Fewer total medications
- Fewer hospitalizations
- > Better self and preventative care skills by the patient and family
- Better drug compliance
- Increased patient satisfaction
- Fewer adverse drug reactions
- > Seamless delivery of care by infusion therapy provider
- > Certified infusion nurses able to provide hands on care in the patient's home
- > Skilled, experience infusion nurse able to teach the patient in self administration, compliance and safety

Overall, these benefits will enhance the quality of care available for infusion therapy patients in a cost effective and accessible manner.

As reflected in the letters of support included in Attachment, Section C, Home Health Services, Item 5, the providers confirm the Applicant's position that approving Coram to have a restricted home health license will be a community benefit, for providers, patients and families.

In summary, the Applicant will have no negative effect on the utilization of existing home health providers, will have a positive effect through more timely discharge and a cost savings for hospital referral sources and will have a positive effect on the home health community through enhanced quality care delivery in the patient's home.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

The Applicant is an existing licensed pharmacy. Through this CON application, it will be adding nursing visits as a limited service home health agency. Currently, the Applicant employees 19 full time equivalents (FTEs) to provide its pharmacy and infusion services. Given its forecasted growth in those business segments, it expects to increase to 24 FTEs during the next two years (without home health). Because the entire management structure, admissions personnel, clerical support and clinical liaisons are already in place, with the addition of the limited home health agency and the addition of skilled nursing visits, the Applicant will only need to add additional registered nurses to provide such services.

The following table provides the number of full time equivalents employed by the Applicant, the current average salary per year for the existing operations, and forecasted FTEs for the two projection years as shown in the Projected Data Chart for the Existing Business included within the Attachments.

Additionally, the table identifies the incremental FTEs to provide the skilled nursing visits upon establishment of the limited home health service agency as the subject of this CON application.

	Current FTEs	t – Forecasted Staffing Current Salary	Forecasted F	TEs by Year
Position	2014		Year One	Year Two
Existing Operations			·	
Administration	2.00	\$75,000	2.00	2.00
Clinical Liaison	1.00	\$70,000	1.00	1.00
Territory Manager	1.00	\$70,000	1.00	1.00
Pharmacist	3.00	\$108,000	3.00	4.00
Pharmacy Technician	3.00	\$34,000	4.00	4.00
Dietician	1.00	\$62,000	1.00	1.00
Admissions	2.00	\$34,500	2.50	3.00
Registered Nurses	1.00	\$70,000	2.00	3.00
Customer Support	2.00	\$31,500	2.00	2.00
Warehouse Worker	2.00	\$35,000	2.00	2.00
Clerical	1.00	\$27,000	1.00	1.00
	19.0		21.50	24.00
Proposed Operations –	Limited Home Healt	h – Skilled Nursing		
Registered Nurses	0.00	(*)	1.95	2.15

	Projected Data Char	t – Forecasted Staffing	and Salaries	
	Current FTEs	Current Salary	Forecasted F	TEs by Year
Position	2014		Year One	Year Two
Combined Total FTE	S			
Total	19.0		23.45	26.15

^(*) The planned salary is \$82,000 in year one, 2015 dollars.

Average salaries by position are based on actual salaries of the Applicant since it is an existing licensed operation. These salaries are reasonably competitive as the Applicant has been able to successfully recruit and retain its employees as a longstanding West Tennessee employer. Average salaries for future periods were adjusted for inflationary purposes in the projected data chart. In addition to salaries, all full time employees have a benefit package. This package includes sick, holiday, vacation and insurance benefits and averages approximately 20 percent of salaries. Pool employees are not eligible for benefits.

The total number of RN FTEs for skilled nursing visits in year two will be 2.15 FTEs, an increase of 0.20 from year one, as there will only be 21 more patients in year two (228) compared to year one (207).

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

Coram Alternate Site Services, Inc. is an existing licensed pharmacy operating in West Tennessee. As noted in Section C, Question 3 above, it is fully staffed to provide its current and future pharmacy services in accordance with its budget. With respect to the addition of nursing visits, Coram will add registered nurses to provide the services. Based on the number of visits anticipated, the average duration of a visit and travel time, Coram will recruit 1.95 full time equivalent (FTE) nurses in year one and 2.15 in year two. It is confident with its existing licenses and relationships in the community that it will successfully recruit the nurses it requires to provide the nursing visits in accordance with its projections.

Geographic placement will be determinant on the number of patients in the area and their needs. The Applicant will place one full time CRNI in Memphis, with a pool of between 8-15 per diem/per visit CRNIs located near larger population centers throughout the service area (e.g., Jackson to the east, Covington and Trenton) will be sufficient to cover the anticipated patient population to be served by this limited service home health agency.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

Coram Alternate Site Services, Inc. is an existing licensed pharmacy operation in West Tennessee (and elsewhere). It has received, reviewed, understands and intends on complying with all applicable licensure requirements of the Department of Health as it relates to medical and clinical staff. It also intends on complying with all applicable Medicare and Medicaid/Tenncare requirements regarding medical and clinical staff.

The Applicant has appropriate credentialing standards, quality assurance policies and programs, utilization review policies and programs, record keeping protocols and staff education requirements in place that will be expanded as applicable to the home health agency services.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

Coram Alternate Site Services is an existing licensed pharmacy which recognizes the importance of training and education, both for students as well as healthcare professionals not familiar with Coram's unique specialty of infusion. Accordingly, throughout Tennessee, Coram has the following educational and training relationships in place:

- David Lipscomb University: Pharmacists
- University of Tennessee: Pharmacists
- > Various Home Health Agency: Train nurses in infusion services
- > Physician Offices In-services on: Starting an IV; specialty drugs; infusion equipment (pump and set up); infusion of specialty drugs
- ➤ Hospital Case Managers and Dietician In-Services on: Types of infusion which are safe to administer at home; sending home on TPN; infusion equipment

It is also the Applicant's intention to add pharmacy technician training for vocational schools when appropriate.

With the approval of this CON application for limited home health services, it is Coram's intent to expand the above relationships to additionally include other universities and various schools of nursing to provide experiential training on infusion service.

Clearly the Applicant will continue its current commitment to the training of both students and area healthcare professionals in the specialty niche in which Coram operates.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

Coram Alternate Site Services has reviewed and understands the licensure requirements of the Department of Health applicable for the proposed limited service home health agency. Additionally, the Applicant is fully cognizant of the requirements for a home health agency as promulgated by the Centers for Medicare and Medicaid Services.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure:

Tennessee Department of Health, Board of Licensing in accordance

with Chapter 1200-08-26 Standards for Home Health Agencies

Accreditation:

The Joint Commission

No measures other than those in the ordinary course of business and consistent with the Applicant's policies and procedures were taken in response to the latest licensing survey because that survey noted no deficiencies.

The Applicant is accredited organizationally by the Joint Commission, which may or may not result in a survey of the Applicant's Memphis location. A copy of the Applicant's latest Joint Commission documentation is attached.

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

The Applicant is currently licensed by the State of Tennessee as a Pharmacy. It is also accredited by The Joint Commission. It is enrolled in both Medicare and Medicaid (TennCare) to provide services to these population groups. The Applicant also has a licensed limited service home health agency serving 38 counties in Middle Tennessee; that license is included in Attachment, Section A, Item 4.3.

(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Coram Alternate Site Services, Inc.'s Memphis Branch is licensed as a pharmacy. To the best of our knowledge, the Memphis, Tennessee Branch has not incurred any deficiencies, violations and/or fines. Attachment, Section C, Contribution to Orderly Development, Item 7(d) includes the copy of the most recent inspection of the Memphis Branch. No deficiencies were noted so there is no applicable plan of correction.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

From time to time Coram is subject to ordinary course surveys, reviews and recertifications by governmental agencies and, accordingly, Coram has incurred non-material deficiencies, violations and/or fines. No such surveys, reviews and re-certifications have led to any loss or limitations of licensure by Coram or have had or are expected to have a material impact on Coram's operations or financial standing or have had or expected to have material impact on Coram's operations or financial standing. To the best of our knowledge, the Memphis, Tennessee Branch has not incurred any such deficiencies, violations and/or fines.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

The Applicant has never received any final civil or criminal judgments for fraud or theft. Furthermore, its principals and officers have never received any final civil or criminal judgments for fraud or theft against. Lastly, to the best of our knowledge, any person or entity with more than 5% ownership interest in the Applicant has never received any final civil or criminal judgments for fraud or theft.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

Coram Alternate Site Services, Inc. confirms that if approved, it will timely provide the Tennessee Health Services and Development Agency, Department of Health and/or any designated reviewing agency information concerning the number of patients treated, number and type of procedures performed and other data as required. It will submit its Joint Annual Report on a timely basis which also includes statistical and financial information for the home health operation as well as patient migration information utilized by the State. Furthermore, to the extent reporting requirements are altered or adjusted in future periods, Coram agrees to comply with any newly adopted reporting requirements.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

A copy of the notice of intent with the mast and dateline intact is provided on the following page as required.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-3601 et seq., and the Rules of the Health Services and Development Agency, that Coram Alternate Site Services, Inc. d/b/a Coram CVS/ specialty Infusion Services, owned by CVS Caremark Corporation, with an ownership type of for profit corporation to be self-managed, intends to file an application for a Certificate of Need for the establishment of a limited service home health agency only to provide and administer home infusion products and related infusion nursing services ancillary to its pharmacy services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports within the following Tennessee counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, Madison, McNairy, Obion, Perry, Shelby, Stewart, Tipton, Wayne, and Weakley, from its current licensed home infusion pharmacy located at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee 38134 with an estimated project cost to not exceed \$98,000. Coram Alternate Site Services, Inc. is currently licensed in the following counties: Bedford, Bledsoe, Cannon, Cheatham, Clay, Coffee, Cumberland, Davidson, DeKalb, Dickson, Franklin, Giles, Grundy, Hamilton, Hickman, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Marion, Marshall, Maury, Montgomery, Overton, Putnam, Rhea, Robertson, Rutherford, Sequatchie, Smith, Sumner, Trousdale, Warren, White, Williamson, and Wilson.

The anticipated filing date of the application is June 6, 2014.

The contact person for this project is Alix Coulter Cross, Attorney, who may be reached at Harwell Howard Hyne Gabbert & Manner PC, 333 Commerce Street, Ste. 1500, Nashville, TN 37201, 615/256-0500.

Upon written request by interested parties a local fact-finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, Tennessee 37243

The published letter of intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

- 1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
- 2. If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.

It is the Applicant's intent to expeditiously proceed with the implementation of Coram Alternate Site Services, Inc.'s limited home health services as soon as certificate of need approval is obtained. Based on the project completion forecast as presented on the following page, the home health agency is expected to be licensed approximately 7 months from the CON application submission, or approximately three months from the CON hearing, beginning operations on or before January 1, 2015.

PROJECT COMPLETION FORECAST WEST TENNESSEE (MEMPHIS BRANCH)

Enter the Agency projected Initial Decision	on date, as	published in	TCA 68	3-11-1609(c)
---	-------------	--------------	--------	------------	----

24	-Se	D-1	4

Assuming the CON approval becomes the final agency action on that date, indicate the number of days from the above agency decision date to each phase of completion forecast.

Pha	ase	Days Required	Anticipated Date (Month/Year)
1	Architectural and engineering contract signed		
2	Construction documents approved by the TN Dept of Health		<u>你这</u> "你可是用好多多数
3	Construction contract signed		
4	Building permit secured		
5	Site preparation completed		CATE RESTRECTION
6	Building construction commenced		
7	Construction 40% complete		
8	Construction 80% complete	N/##1 00 # 75 F W	
9	Construction 100% complete (approved for occupancy)		
10	* Issuance of license	95	December-14
11	* Initiation of service	5	January-15
12	Final Architectural Certification of Payment		
13	Final Project Report Form (HF0055)		

For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect actual issue date.

AFFIDAVIT

STATE OF COLORADO
COUNTY OF DENVER, COLORADO
MICHAEL E. DELL, SVP, GC & SECRETARY being first duly sworn, says that he/she
is the applicant named in this application or his/her/its lawful agent, that this project will be
completed in accordance with the application, that the applicant has read the directions to
this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-
11-1601, et seq., and that the responses to this application or any other questions deemed
appropriate by the Health Services and Development Agenc are true and complete. MICHAEL E. DELL, SVP, GC & SECRETARY
SIGNATURE/TITLE
Sworn to and subscribed before me this 20TH day of MAY (Month), 2014 a Notary
Public in and for the County/State of DENVER, COLORADO
PATRICIA V IVANCICH NOTARY PUBLIC STATE OF COLORADO NOTARY ID # 20034019486 MY COMMISSION EXPIRES JUNE 12, 2015 NOTARY PUBLIC
My commission expires JUNE 12 , 2015 (Month/Day) (Year)

CORAM ALTERNATE SITE SERVICES, INC. CERTIFICATE OF NEED APPLICATION TO ESTABLISH A LIMITED SERVICE HOME HEALTH AGENCY WEST TENNESSEE APPLICATION ATTACHMENTS

JUNE 2014

APPLICATION ATTACHMENTS

ATTACHMENT, SECTION A, ITEM 4.4 CORAM ALTERNATE SITE SERVICES, INC. CORAM LOCAL BRANCH FINANCIAL STATEMENTS

Summary P&L Base and AIS Memphis	4.40	Coram Inc. ctual/Budget 2012	2013
Net Revenue TPN Antibiotic Cardiovascular Pain Management Core Branch IVIG SQIG Alpha-1 Enzymes Remicade/RA Tysabri Biotherapy Other Specialty Specialty Branch Non-Core Therapy All Other Net Revenue	1,185,848 1,296,741 85,526 34,588 2,602,703 816,021 641,656 1,689,410 0 0 (19) 3,147,068 218,151 (10,827) 5,957,094	954,146 1,394,196 213,079 29,439 2,590,860 865,754 535,543 1,471,402 0 0 0 2,872,698 116,938 (16,468) 5,564,028	591,902 1,326,836 147,110 50,040 2,115,887 1,177,407 429,895 1,569,197 0 0 12,228 3,188,726 49,891 (15,266) 5,339,239
Patient Months TPN Antibiotic Cardiovascular Pain Management Core Branch IVIG Vivaglobin Alpha-1 Enzymes Remicade Tysabri Biotherapy Other Specialty Specialty Branch Non-Core Therapy All Other Patient Months	417 621 19 38 1,095 157 133 175 0 0 0 471 382 0	486 540 35 40 1,101 156 113 168 0 0 0 5 442 261 0 1,804	377 488 31 41 937 161 81 168 0 0 2 412 183 0 1,532
Gross Prod Mgn Gross Prod Mgn %	2,603,913 43.7%	2,520,310 45.3%	2,111,686 39.6%

Summary P&L Base and AIS Memphis	141 2011	Coram Inc. Actual/Budget 2012	2013
Nursing Total Total Labor General Expenses Total Nursing % of Net Revenue	225,440 18,685 244,125 4.1%	245,342 1,300 246,642 4.4%	143,477 7,253 150,730 2.8%
Pharmacy Total Total Labor General Expenses Total Pharmacy % of Net Revenue	674,280 20,992 695,272 11.7%	821,719 12,695 834,414 15.0%	784,547 16,062 800,610 15.0%
Warehouse Total Labor General Expenses Total Warehouse % of Net Revenue	55,700 10,802 66,502 1.1%	77,649 15,539 93,187 . 1.7%	59,132 12,206 71,339 1.3%
Delivery Total Labor General Expenses Total Delivery % of Net Revenue	0 84,487 84,487 1.4%	81,107 81,107	0 68,903 68,903 1.3%
Branch Administration Total Labor General Expenses Total Branch Admin % of Net Revenue	190,189 27,071 217,261 3.6%	86,228 25,326 111,554 6 2.0%	93,617 16,671 110,288 2.1%
Facilties Branch Total Labor General Expenses Total Facilities Branch % of Net Revenue	190,893 190,893 3.2%	195,963 196,227	78 208,679 208,757 3.9%
HPRs Total Labor General Expenses Total HPRs % of Net Revenue	42,632 (42,632 0.7%	675 50,089	87,098 868 87,966 1.6%
All Other (Dieticians) Total Labor General Expenses Total All Other % of Net Revenue	28,464 294 28,759 0.5%	85 27,168	26,605 117 26,723 0.5%
Clinical Services Total Labor General Expenses Total Clinical Services % of Net Revenue	1,174,074 353,225 1,527,29 8 25.6%	332,014 1,590,299	1,107,457 329,892 1,437,350 26.9%

Summary P&L Base and AIS Memphis		Coram Inc. ctual/Budget 2012	2013
Admissions Total Labor General Expenses Total Admissions % of Net Revenue	0	24,089	52,635
	0	549	0
	0	24,638	52,635
	0.0%	0.4%	1.0%
PFS Total Labor General Expenses Total PFS % of Net Revenue	185,256	209,299	205,371
	19,665	22,084	24,933
	204,920	231,384	230,305
	3.4%	4.2%	4.3%
Selling Total Labor General Expenses Total Selling % of Net Revenue	143,320	171,288	171,238
	15,882	24,610	21,534
	159,202	195,898	192,772
	2.7%	3.5%	3.6%
All Departments OpEx Wages Expense Benefits Expense Bonus/Commission Contract Labor Enteral Chargeback Severance Expense Total Labor % of Net Revenue	1,200,437	1,344,974	1,269,676
	158,361	179,422	162,459
	1,000	300	0
	142,851	138,265	119,790
	0	0	(15,225)
	0	0	0
	1,502,649	1,662,961	1,536,701
	25.2%	29.9%	28.8%
Marketing Office Expenses Rent and Cam Utilities Total Cleaning & Other Services Shipping and Delivery Equipment Expenses Training/Education Placement Fees/Recuiting Travel and Entertainment Professional Fees & Lic Collection/Consulting Fees Real Personal & Sales Tax Insurance Other General Expenses General Expenses % of Net Revenue	7,822 24,319 79,760 53,286 4,378 85,546 24,271 667 397 32,219 4,654 5,477 19,530 16,915 29,532 388,771 6.5%	10,988 29,097 94,354 49,968 5,982 84,968 20,065 4,100 233 27,500 250 1,213 16,791 14,379 19,369 379,257 6.8%	1,728 25,832 105,466 49,966 5,928 70,827 18,234 0 209 29,289 111 0 22,732 18,610 27,484 376,415 7.0%
Total All Depts OpEx	1,891,420	2,042,218	1,913,116
% of Net Revenue	31.8%	36.7%	35.8%
Bad Debt	112,656	221,269	67,216
% of Net Revenue	1.9%	4.0%	1.3%
EBITDA % of Net Revenue	599,837	256,822	131,354
	10.1%	4.6%	2.5%
Depreciation	19,365	10,392	12,001
Net Income	580,472	246,430	119,353

ATTACHMENT, SECTION B, PROJECT DESCRIPTION, ITEM II (A)

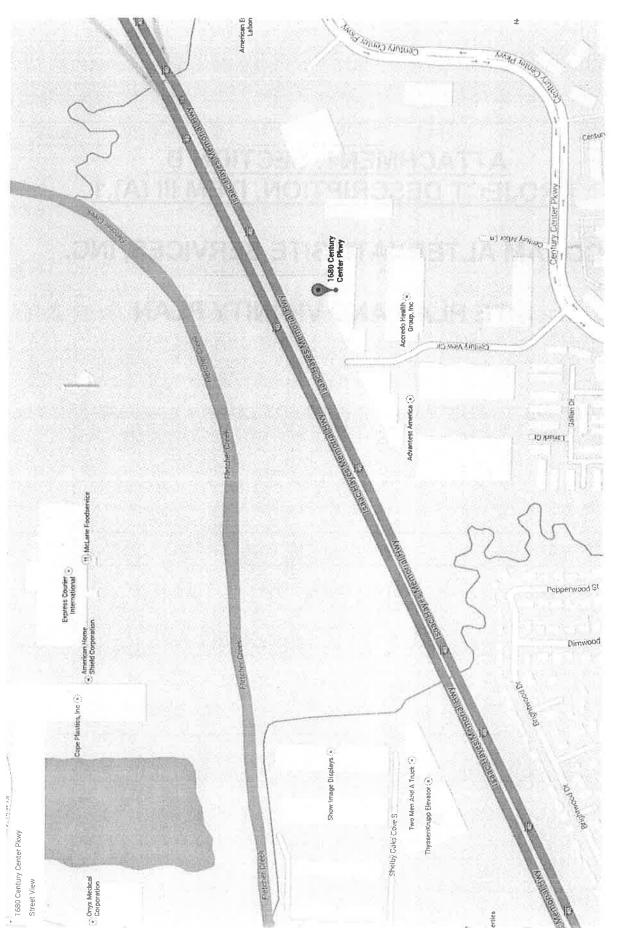
CORAM ALTERNATE SITE SERVICES, INC.
SQUARE FOOTAGE AND COST CHART

SQUARE FOOTAGE AND COST PER SQUARE FOOTAGE CHART

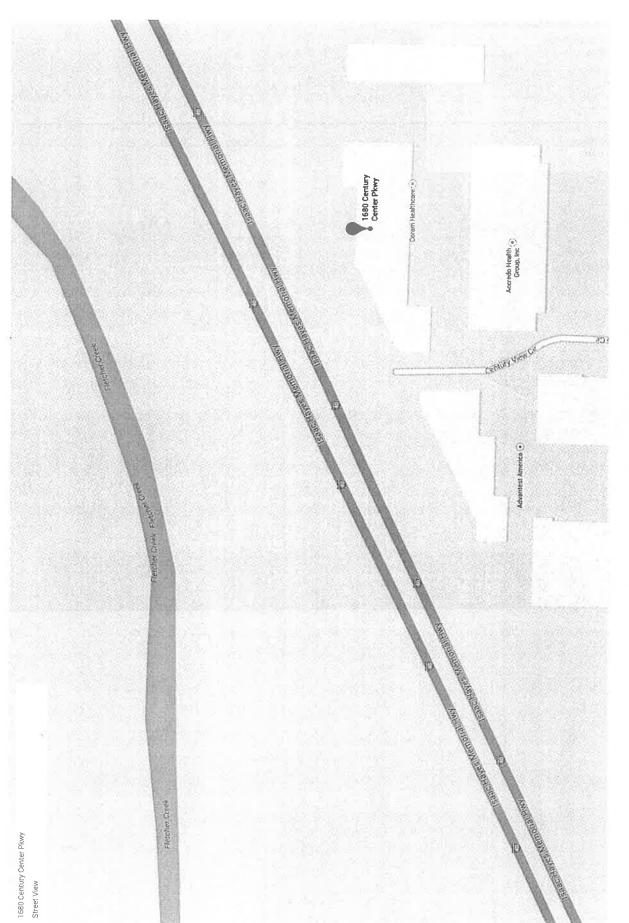
A. Unit / Department	Existing	Existing SF	Temporary	Proposed Final	Proposed	Proposed Final Square Footage	Footage	Prc	Proposed Final Cost/SF	Cost/SF	
	Location		Lucation	Location	Renovated	New	Total	Renovated	New	Total	
Entry		91			0	0	91			69	,
Office		173			0	0	173			s	4
Сору Коот		197			0	0	197			69	Ι.
MDF/IT		55			0	0	55			69	Ι.
Office		120			0	0	120			69	Ι.
Clean		252			0	0	252				
Ante		83			0	0	83			49	Ι.
Prep		437			0	0	437				
Staging		293			0	0	293			69	Γ.
Open Office		3,340			0	0	3,340			69	Τ.
Toilet		106			0	0	106			S	Γ.
Hall		114			0	0	114			69	Τ.
Toilet		43			0	0	43			69	Ι.
Break		213			0	0	213			4	Ι.
Janitor		71			0	0	71			6	Ι.
Office - BrCoor		132			0	0	132				Γ
Conference		252			0	0	252				Г
Office		120					120				T
Office		120	2.				120				Γ
Office		120					120				Ī
Office		120					120				Γ
B. Unit/Depart. GSF Sub-Total		6,452			0	0	6 452			65	
C. Mechanical/Electrical GSF		314					314				
D. Circulation/Structure GSF					0	0				ь	
E. Total GSF		99,768			0	0	9929			69	

ATTACHMENT, SECTION B, PROJECT DESCRIPTION, ITEM III (A),1 CORAM ALTERNATE SITE SERVICES, INC. SITE PLAN AND VICINITY PLAN

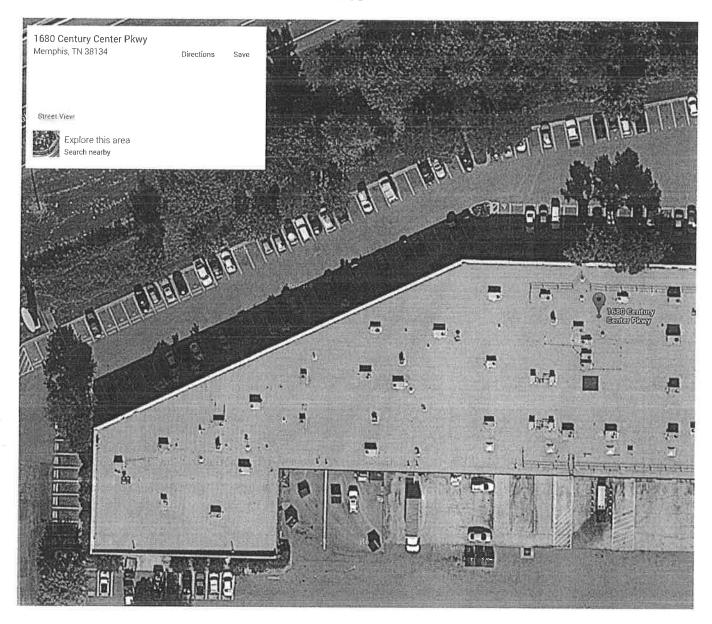
1680 Century Center Pkwy - Google Maps



Map date @2014 Google 200 ft

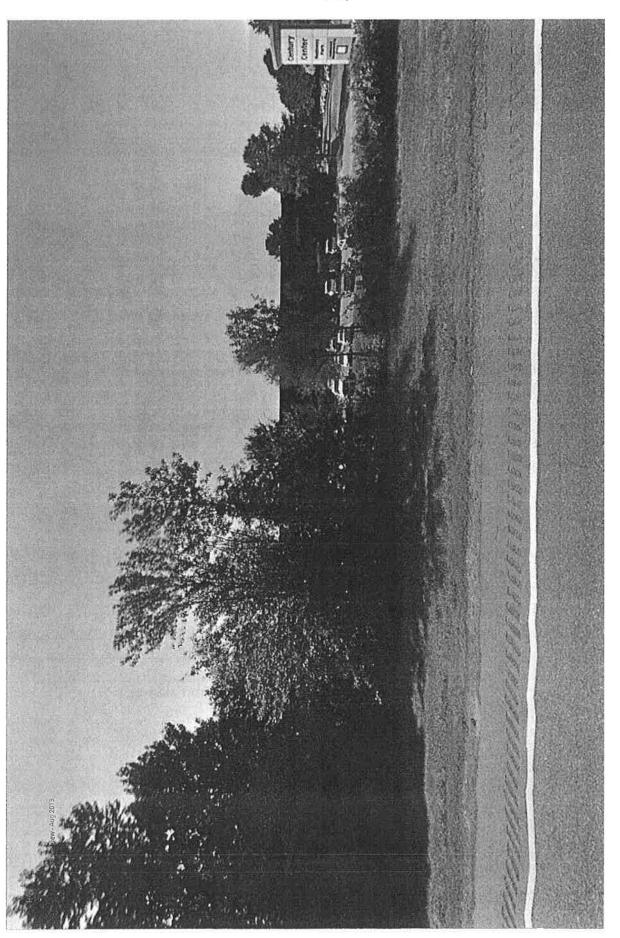


Map data @2014 Google 100 ft



Map data ©2014 Google 20 ft

1680 Century Center Pkwy - Google Maps



CHEYENNE JOHNSON Assessor of Property

Property Location and Owner Information	2014Appraisal and Assessment Information		
Parcel ID: 089046 00018	Class: EXEMPT		
	Land Appraisal:	\$ 655,800	
Property Address: 1680 CENTURY CENTER PKWY	Building Appraisal:	\$ 3,004,700	
Municipal MEMPHIS	Total Appraisal:	\$ 3,660,500	
Jurisdiction:			
Neighborhood 00604F51	Total Assessment:	\$ C	
Number:			
Tax Map Page: 117L	Greenbelt Land:	\$ C	
Land Square	Homesite Land:	\$ C	
Footage:	Homesite Building:	\$ C	
Acres: 5.8000	Greenbelt Appraisal:	\$ 0	
Lot Dimensions: 252648 SF	Greenbelt Assessment:	\$ 0	
Subdivision Name: WHITTEN/I-40 PUD PH 9			
Subdivision Lot 1	Click Here for 2013	Values	
Number:	View: Assessor's GIS Map		
Plat Book and 159-74	View: GIS Parcel N	Мар	
Page:			
Number of 1			
Improvements:			
Owner Name: INDUSTRIAL DEVELOPMENT BOARD OF THE			
CITY OF MEMPHIS AND COUNTY OF SHELBY			
TN (THE)			
In Care Of: EVANS PETREE			
Owner Address: P O BOX 771020			
Owner MEMPHIS, TN 38177 1020	1		
City/State/Zip:			

Commerci	al Structure Information
Land Use:	- LOFT MANUFCT
Total Living Units:	0
Structure Type:	FLEX WAREHOUSE
Year Built:	1995
Investment Grade:	A
Building Square Footage:	77925

Other Buildings on Site for this Property See Permits Filed for this Property See Sales Data for this Property

Disclaimer: The information presented on this web site is based on the inventory of real property found within the jurisdiction of the county of Shelby in the State of Tennessee. Shelby County assumes no legal responsibility for the information contained within this web site. This is not a bill and does not serve as a notice or invoice for payment of taxes nor does it replace scheduled notices mailed to property owners.

Home | Contact | Ethics | F. A. Q. | Filing Tools | Forms | Glossary | History | Links | Mortgage Calculator | Recording Statistics

Tom Leatherwood

Shelby County Register of Deeds

Property Data INDUSTRIAL DEVELOPMENT BOARD OF THE CITY OF MEMPHIS AND COUNTY OF SHELBY TN (THE) 1680 CENTURY CENTER PKWY Property Address Tax District MEMPHIS 089046 00018 Parcel ID: Тах Мар: 117L TIFE PDE Year Built Lot Number WHITTEN/I-40 PUD PH 9 Subdivision Name: Plat BK. & PG. 158-74 Dimensions 252648 SF Land Total: Total Acres: 5,80 0 P O BOX 4900 EPROPERTY TAX SCOTTSDALE, AZ 85261

- LOFT MANUFCT Use Zoning County Tax Info Memphis Tax Info Appraisal Appraisal Info

EXEMPT

Class

Recent and Comparable Sales Search

Property Transactions

Item 1	
Inst#:	- <u>05104651</u>
Inst Type:	SPECIAL WARRANTY DEED
Sales Date:	07/01/2004
Sales Price:	
Item 2	
Inst#:	-GF6101
Inst Type:	QUIT CLAIM
Sales Date:	11/26/1996
Sales Price:	
Item 3	
Inst#:	-GF6102
Inst Type:	SPECIAL WARRANTY DEED
Sales Date:	11/26/1996
Sales Price:	13,240,000
Item 4	
Inst#:	-GF6102
Inst Type:	SPECIAL WARRANTY DEED
Sales Date:	11/26/1996
Sales Price:	13,240,000

NAD83 Coordinates

Y Coordinate:



Property data, transactions and parcels reflect information from the April 2013 certified tax roll. More recent information is available at Property Search.

Property tax maps and parcel boundaries do not reflect accurate survey information or exact legal ownership boundaries but are only provided for general information purposes.

Property tax maps are provided to the County Register by the County Assessor's office "on or before October 1 of each year" according to T.C.A. 67-5-806.

Aerial Map - 2004 is from the 2004 USGS flyover. Parts of North and Southwest Shelby County were not included in this flyover.

FEMA data is based on their Q3 Flood Data product, More information is available at http://www.fema.gov/plan/prevent/fhm/fq_q3.shtm.

Soil data is derived from the United States Department of Agriculture, Natural Resources Conservation Service. More information is available at http://websoilsurvey.nrcs.usda.gov/app/WebSoilSurvey.aspx

Cemetery points were provided by the Shelby County Historical Commission and do not reflect accurate survey information or exact cemetery locations within parcels. The information provided is for general purposes only.



Search Type: Address 1680 CENTURY CENTER PKW

To optimize search, leave street direction and type off. ie., MAIN instead of N MAIN ST.

Search Clear Parcels

- Streets
- \square
- 2ft Contours 2006
- FEMA Flood Plain \Box
- Cemeteries
 - AERIALS
- Parks
- Streams
- Parcel IDs
- Soil Data

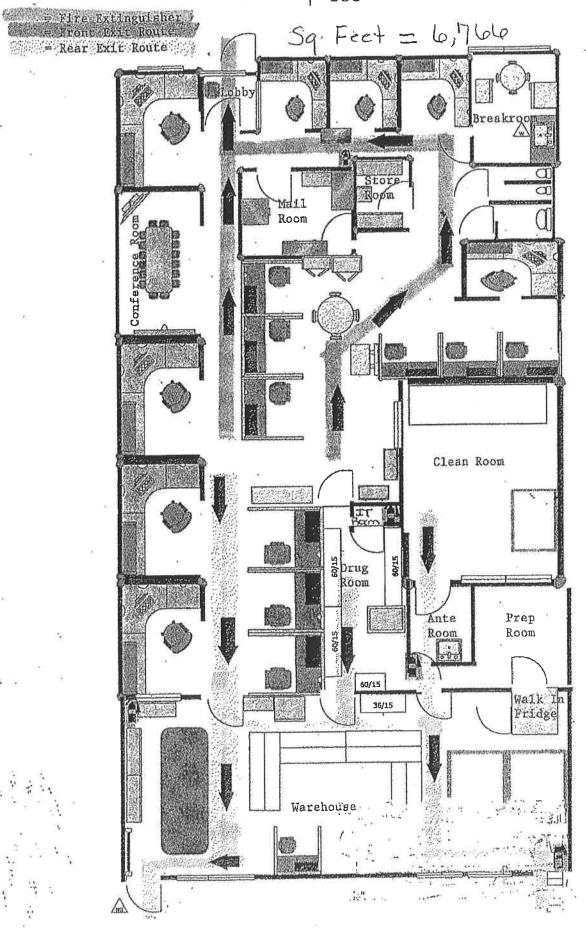
CITY BOUNDARIES

LEGENDS

ATTACHMENT, SECTION B, PROJECT DESCRIPTION, ITEM IV

CORAM ALTERNATE SITE SERVICES, INC. FLOOR PLAN

Memphis

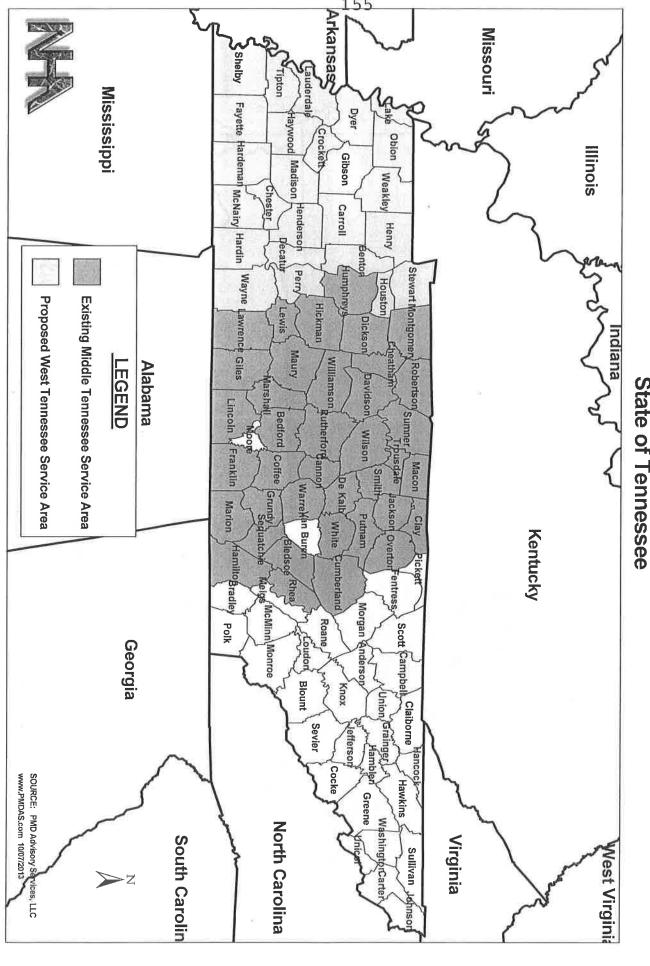


4.

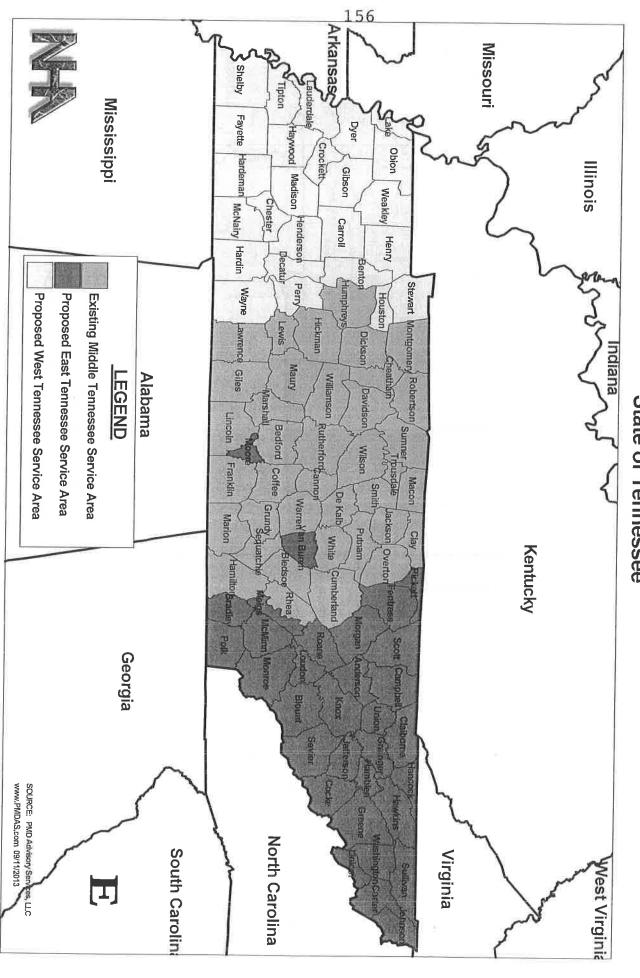
ATTACHMENT, SECTION B, PROJECT DESCRIPTION, ITEM V

CORAM ALTERNATE SITE SERVICES, INC. STATE OF TENNESSEE MAP WITH SERVICE AREA

Existing and Proposed Restricted Service Home Health Service Areas Coram Alternate Site Services, Inc. State of Tennessee



Existing and Proposed Restricted Service Home Health Service Areas Coram Alternate Site Services, Inc. State of Tennessee



ATTACHMENT, SECTION C, HOME HEALTH SERVICES, ITEM 1

CORAM ALTERNATE SITE SERVICES, INC.

STATE OF TENNESSEE HOME HEALTH NEED BY COUNTY

Joint Annual Report of Home Health Agencies - 2013 Final* Comparison of Population Based Need Projection vs. Actual Utilization (2018 vs. 2013)**

Such Edward	Agencies	Agencies	Total						Need or
Service	Licensed to	Report	Patients	Estimated		Projected	Projected	Projected Need	(Surplus)
Area	Serve	Serving	Served	2013 Pop.	Use Rate	2018 Pop.	Capacity	(.015 x 2018 Pop.)	for 2018
Tennessee	1,619	1,457	175,924	6,528,014	0.0269	6,833,509	184,157	102,503	(81,654
Anderson	22	19	2,893	76,182	0.0380	77,851	2,956	1,168	(1,789
Bedford	20	19	1,120	46,700	0.0240	50,566	1,213	758	(454
Benton	11	10	667	16,315	0.0409	16,104	658	242	(417
Bledsoe	10	8	462	12,698	0.0364	12,599	458	189	(269
Blount	18	18	2,507	126,809	0.0198	135,171	2,672	2,028	(645)
Bradley	16	14	2,021	102,235	0.0198	107,481	2,125	1,612	(512)
Campbell	21	18	1,715	41,163	0.0417	42,566	1,773	638	(1,135)
Cannon	19	16	423	14,013	0.0302	14,540	439	218	(221)
Carroll	13	13	1,246	28,213	0.0442	27,831	1,229	417	(812)
Carter	12	11	2,072	57,228	0.0362	57,680	2,088	865	(1,223)
Cheatham	24	25	772	39,603	0.0195	40,765	795	611	(183)
Chester	14	13	563	17,355	0.0324	17,999	584	270	(314)
Claiborne	19	15	2,002	32,457	0.0617	33,280	2,053	499	(1,554)
Clay	8	6	250	7,719	0.0324	7,673	249	115	(133)
Cocke	16	14	1,467	36,330	0.0404	38,615	1,559	579	(980)
Coffee	20	16	1,874	53,784	0.0348	56,841	1,981	853	(1,128)
Crockett	13	12	537	14,568	0.0369	14,683	541	220	(321)
Cumberland	15	13	1,601	57,370	0.0279	60,292	1,683	904	(778)
Davidson	32	32	14,912	649,507	0.0230	682,330	15,666	10,235	(5,431)
Decatur	17	14	638	11,773	0.0542	12,080	655	181	(473)
DeKalb	21	16	469	18,918	0.0248	19,125	474	287	(187)
Dickson	25	24	1,617	50,596	0.0320	51,964	1,661	779	(881)
Dyer	11	10	1,671	38,205	0.0437	38,427	1,681	576	(1,104)
Fayette	26	23	713	40,081	0.0178	44,888	799	673	(125)
Fentress	10	7	1,015	18,290	0.0555	18,987	1,054	285	(769)
Franklin	17	12	1,424	41,099	0.0346	42,122	1,459	632	
Gibson	15	14	1,924	50,748	0.0379	52,163	1,439	782	(828)
Giles	12	11	1,001	29,325	0.0373	29,285	1,000		(1,195)
Grainger	22	20	886	22,994	0.0385	23,675	912	439	(560)
Greene	20	17	2,454	69,888	0.0353	71,594	2,514	355	(557)
Grundy	18	16	529	13,396	0.0395	13,293	525	1,074	(1,440)
Hamblen	19	17	2,835	63,763	0.0393	65,570	2,915	199	(326)
Hamilton	16	16	8,038	345,447	0.0443	353,577		984	(1,932)
Hancock	14	11	682	6,652	0.0233		8,227	5,304	(2,924)
Hardeman	17	15	917	26,492	0.1023	6,640	681	100	(581)
Hardin	16	14	1,157	25,968	0.0346	26,067	902	391	(511)
Hawkins	21	18	2,148			26,244	1,169	394	(776)
Haywood	15	13	612	57,273	0.0375 0.0336	58,164	2,181	872	(1,309)
Henderson	14	13	1,015	18,199		18,009	606	270	(335)
Henry	10	10	1,013	28,080	0.0361	28,631	1,035	429	(605)
Hickman	18	17	725	32,595	0.0394	32,956	1,297	494	(803)
Houston	12	11		24,393	0.0297	24,698	734	370	(364)
Humphreys	16		281	8,358	0.0336	8,447	284	127	(157)
Jackson	12	14	803	18,488	0.0434	18,561	806	278	(528)
Jefferson			402	11,355	0.0354	11,495	407	172	(235)
	20	19	1,749	53,006	0.0330	56,872	1,877	853	(1,023)
Johnson	5	5	907	18,126	0.0500	18,127	907	272	(635)
Knox	24	23	9,976	448,093	0.0223	475,569	10,588	7,134	(3,454)
_ake	6	5	325	9,795	0.0332	9,468	314	142	(172)

Joint Annual Report of Home Health Agencies - 2013 Final* Comparison of Population Based Need Projection vs. Actual Utilization (2018 vs. 2013)**

	Agencies	Agencies	Total	LE CHARLES (ALLES)				The same of the sa	Need or
Service	Licensed to	Report	Patients	Estimated		Projected	Projected	Projected Need	(Surplus)
Area	Serve	Serving	Served	2013 Pop.	Use Rate	2018 Pop.	Capacity	(.015 x 2018 Pop.)	for 2018
Lauderdale	14	11	857	27,465	0.0312	27,125	846	407	(440)
Lawrence	15	12	1,667	42,280	0.0394	42,387	1,671	636	(1,035)
Lewis	12	10	402	12,111	0.0332	12,224	406	183	(222)
Lincoln	14	12	1,062	33,979	0.0313	35,697	1,116	535	(580)
Loudon	23	21	1,572	50,356	0.0312	53,192	1,661	798	(863)
McMinn	17	17	1,807	53,004	0.0341	54,203	1,848	813	(1,035)
McNairy	15	13	1,089	26,408	0.0412	27,299	1,126	409	(716)
Macon	17	15	849	22,957	0.0370	24,121	892	362	(530)
Madison	16	15	3,121	99,153	0.0315		3,179	1,515	(1,664)
Marion	16	15	729	28,448	0.0256		743	435	(308)
Marshall	21	17	816	31,159	0.0262	32,015	838	480	(358)
Maury	23	21	2,412	82,029	0.0294	83,256	2,448	1,249	(1,199)
Meigs	18	16	346	12,064	0.0287	12,643	363	190	(173)
Monroe	19	19	1,517	45,664	0.0332	48,088	1,598	721	(876)
Montgomery	19	20	2,903	184,087	0.0158		3,163	3,008	(154)
Moore	13	10	97	6,369	0.0152	6,401	97	96	(1)
Morgan	21	21	472	21,826	0.0216		476	330	(146)
Obion	12	12	1,280	31,536	0.0406	31,222	1,267	468	(799)
Overton	14	11	742	22,376	0.0332	22,967	762	345	(417)
Perry	11	6	258	7,971	0.0324	8,096	262	121	(141)
Pickett	8	6	271	5,045	0.0537	4,943	266	74	(191)
Polk	11	11	427	16,654	0.0256		425	249	(176)
Putnam	16	14	2,405	75,646	0.0318	82,623	2,627	1,239	(1,387)
Rhea	16	15	927	32,966	0.0281	34,790	978	522	(456)
Roane	24	22	2,354	53,918	0.0437	54,457	2,378	817	(1,561)
Robertson	26	26	1,739	69,336	0.0251	74,371	1,865	1,116	(750)
Rutherford	29	29	5,503	285,141	0.0193	329,446	6,358	4,942	(1,416)
Scott	18	15	835	21,986	0.0380	21,969	834	330	(505)
Sequatchie	14	11	413	14,756	0.0280	16,004	448	240	(208)
Sevier	19	18	2,452	93,637	0.0262	100,362	2,628	1,505	(1,123)
Shelby	27	27	18,064	940,972	0.0192	954,012	18,314	14,310	(4,004)
Smith	17	14	708	19,445	0.0364	20,281	738	304	(434)
Stewart	10	10	339	13,436	0.0252	13,941	352	209	(143)
Sullivan	14		5,259		0.0332	161,136	5,348	2,417	(2,931)
Sumner	26	27	4,160		0.0246		4,504	2,751	(1,753)
Tipton	26	22	1,298		0.0206	67,545	1,392	1,013	(378)
Trousdale	16	14	431	8,046	0.0536		460	129	(331)
Unicoi	13	11	659	18,334	0.0359		665	278	(388)
Union	21	18	371	19,231	0.0193		378	294	(84)
Van Buren	12	11	240	5,456	0.0440		241	82	(159)
Warren	20	15	2,266		0.0562			617	(1,697)
Washington	16	14	4,181	128,537	0.0325			2,076	(2,425)
Wayne	11	9	640	16,887	0.0379		634	251	(383)
Weakley	13	11	1,180	38,255	0.0308		1,218	592	(626)
White	14	9	962	26,612	0.0361	27,974	1,011	420	(592)
Williamson	32	32	2,815		0.0142		3,174	3,350	176
Wilson	28		3,727	121,626	0.0306		4,086		(2,086)
AAIIPOLI	201	91	0,121	121,020	0.0000	100,007	1,000	2,000	(2,000)

^{*}Most recent year of Joint Annual Report data for Home Health Agencies

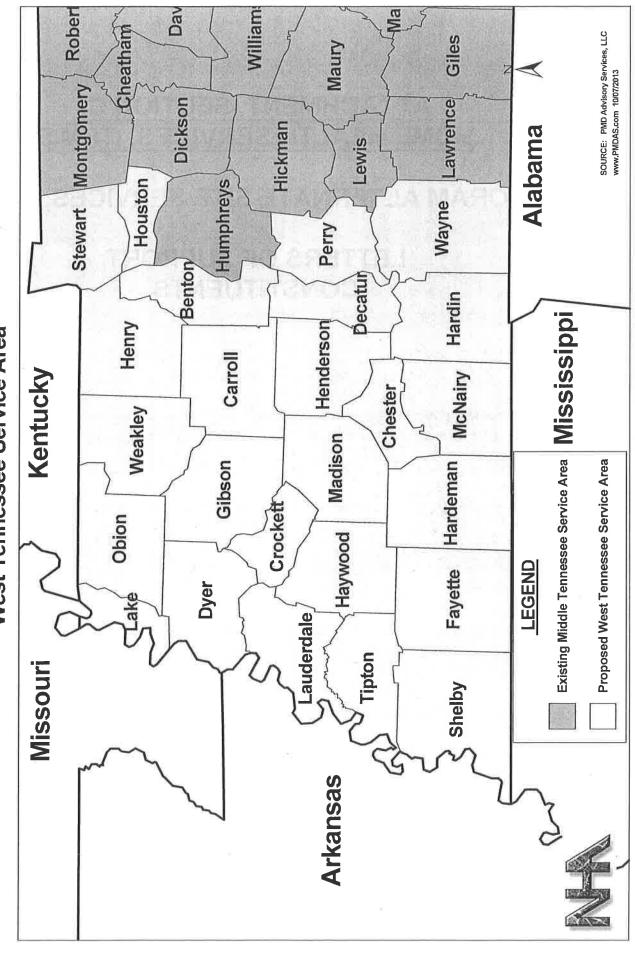
^{**}Data is projected four years from the year the Home Health data was <u>finalized</u>, not the actual year of Home Health data.

ATTACHMENT, SECTION C, HOME HEALTH SERVICES, ITEM 3.1

CORAM ALTERNATE SITE SERVICES, INC.

SERVICE AREA MAP: WEST TENNESSEE WITH SERVICE AREA

Existing and Proposed Restricted Service Home Health Service Areas Coram Alternate Site Services, Inc. West Tennessee Service Area



ATTACHMENT, SECTION C, HOME HEALTH SERVICES, ITEM 5

CORAM ALTERNATE SITE SERVICES, INC.

LETTERS OF SUPPORT CONSTITUENTS

Subject:

FW: Home Health Agency Support

From: Kirby, Nicole

Sent: Monday, October 21, 2013 4:18 PM

To: 'Sally Aldrich'

Subject: RE: Home Health Agency Support

Hi Sally,

Thanks for your support. I understand your unique position. You all do an awesome job in helping us provide quality patient care. We look forward to maintaining and enhancing THIS relationship moving forward.



Nicole Kirby, RN, MBA | Regional Nurse Manager

1680 Century Center Parkway, Suite 12 | Memphis, TN 38134 | P 901.386.3738 | F 901.347.6004 www.coramhc.com Find employment opportunities:

From: Sally Aldrich [mailto:Sally.Aldrich@mlh.org]

Sent: Monday, October 21, 2013 4:04 PM

To: Kirby, Nicole; Donna Burnet **Cc:** Jackie Lloyd; Sonya Glasgow

Subject: RE: Home Health Agency Support

Hi, Ms Kirby -

Please forgive me for taking so long to get back with you. Methodist HH has historically not taken part in providing care for first dose or biologic infusions, you are correct. I think Coram is the right place to maintain this as a specialty function for their nurses trained in this procedure. Methodist does not plan to move in the direction of staffing for first dose or biologics in the home.

Methodist Healthcare recently entered into a Joint Venture with Precision Infusion to provide home infusion services, along with their infusion center located on Park Ave. in east Memphis. While I am in favor of your nursing staff managing your first dose/biologic services, I am not sure my signing a letter of support for your HHA would be approved by Methodist - might be a bit of a conflict there. I would not actively oppose Coram seeking licensure, though, to serve this unique population. Would your CON be specific to first dose, biologics for Coram patients?

thank you for Coram's partnership to care for our patients in Memphis and your work with our agency sally

Sally Aldrich, RN, MSN Administrator, CNO, Affiliated Services Division Home Care, Hospice & Palliative Services ph: 901-516-1413

fax: 901-516-1401 sally.aldrich@mlh.org

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Methodist Le Bonheur Healthcare is proud to once again be named among the Top 100 Integrated Healthcare Networks in the country.

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www.methodisthealth.org www.lebonheur.org

From: Kirby, Nicole [mailto:Nicole.Kirby@coramhc.com]

Sent: Wednesday, October 09, 2013 12:12 PM

To: Sally Aldrich; Donna Burnet

Subject: Home Health Agency Support

Hello Ms Aldrich,

My name is Nicole Kirby. I am Regional Nurse Manager with Coram Specialty Pharmacy. I recently spoke with Ms. Burnet and she suggested you might be able to help me.

As you may well know, Coram has been partnering with agencies like Methodist to meet the needs of patients in the community for many years.

You all do a wonderful job of providing nursing. What you may not know is the challenge we face in getting skilled nursing for some of

our patients receiving biologic products, or those needing first dose in the home, transplant and research protocols. Throughout the nation, Coram provides education to agencies so their nurses can be prepared to care for these patients. Many times however, due to the length of the visits, you all still must refuse the visit due to staffing. For this reason, Coram also has home health to bridge the gap. We typically only employ a few nurses because we are very specialized in our services and we continue to subcontract the majority of our referrals.

Finally, the Memphis branch of Coram would like to apply for licensure to be a HHA. We are asking if you would be willing to sign a letter of support for our endeavor. We look forward to continuing to work together on many referrals in the future.

Please give me a call if you have any questions.



Nicole Kirby, RN, MBA | Regional Nurse Manager

1680 Century Center Parkway, Suite 12 | Memphis, TN 38134 | P 901.386.3738 | F 901.347.6004

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Wanda Lambert P.O. Box 56 Kodak, Tennessee 37764

December 5, 2013

Ms. Melanie Hill Certificate of Need Program c/o Coram Alternate Site Services, Inc.

Dear Ms. Hill:

This past summer, I was given a prescription for home infusion of an Alpha 1 therapy (Glassia). My regimen was for bi-weekly infusions with the therapy taking five to six hours each time. I am a Cigna patient. While Coram was identified to provide me with the therapy, Coram was unable to provide the nursing support to administer the Alpha 1 therapy or even attempt to teach me to self administer.

Unfortunately for me and the healthcare system, while Coram was available to provide the therapy, no home health agency was identified to provide the home nursing support. The only reason I did not have to go to a hospital or an infusion center for treatment is that Coram spent the time (hours and hours, days) contacting home health agencies to solicit such an entity to provide me with home health nursing. In fact, I am well aware that Coram spoke with eleven different agencies – all of whom denied me the needed training and treatment. This delay caused me much anxiety. I can't imagine that it didn't also increase my treatment costs to the healthcare system.

Having treatment needs is hardship enough on a patient. Not being able to reasonably access treatment in a timely manner is even worse.

It is for situations like mine, and for others like me, that I am writing this letter to request your Agency license Coram to provide these types of services. Please approve Coram's certificate of need application to provide limited scope home health services.

Wander Sambert

Wanda Lambert

Michelle Barford 1655 Panoha Drive Germantown, Tennessee 38138

October 7, 2013

Ms. Melanie Hill Certificate of Need Program c/o Coram Alternate Site Services, Inc.

Dear Ms. Hill:

I am a nurse who is also a long term Total Parenteral Nutrition (TPN) patient. My personal experiences and my clinical knowledge are presented here to share with you why it is so very important that your Agency approve Coram's request for a limited service home health agency.

By way of background, I travel extensively and am involved in a patient advocate program. Because of my personal history with access maintenance and having to have a line replaced while out of the country in the past, I requested a Hickman/ CV line repair kit from Coram. Coram provides my TPN products. Coram had the kit available and the requisite program and educational material. However, because the Memphis branch did not have a CON to provide skilled nursing services, the nurses at the branch could not 'touch' me nor provide me with the skilled nursing training. Therefore, I went without this valuable resource.

Sure enough, about two months later, I experienced a fracture on the pigtail portion of my line that resulted in what I consider an unnecessary procedure.

Had Coram had its limited home health agency license, the healthcare systems costs would have been less as (1) I would not have had to had an extra procedures; (2) I could have fixed the problem without outside intervention; (3) the quality of my treatment and experience would have been improved; and (4) outcomes would have been improved. From a personal standpoint, the additional costs I incurred and additional hardships and recovery from the procedure I had to endure would have been avoided. I would have also had better patient outcomes, improving the quality and cost effectiveness of my care and treatment.

For the reasons as stated above, and my knowledge of Coram's commitment to quality service, please approve Coram's CON request for a limited service home health agency. Please contact me if I can be of further assistance.

hichell Bufoz Cordially,

Michelle Barford



October 11, 2013

Ms. Melanie Hill Certificate of Need Program c/o Coram Alternate Site Services, Inc.

Dear Ms. Hill:

My name is Margarita LaMothe, MD. I am an infectious disease and internal medicine physician practicing medicine for more than 25 years. I am board certified by the American Board of Internal Medicine in the specialty of Infectious Disease. I practice in the Memphis area.

Given my specialty, I strongly understand the importance of Coram's role in the at home care of highly acute and/or infectious patients. It is important to me and my patients that Coram's requested certificate of need be approved to establish a limited home health agency in West Tennessee. This will improve my patient's quality of care and these patient outcomes. I speak from full experience of the patient situations and Coram's skill set to recommend this approval.

One example that I had with a patient earlier this year was that the assigned home health agency did not draw the correct labs that I needed to assess my patient's condition. Thinking it was correcting the situation, the home health agency then drew them in the middle of the day. This patient was on a 10AM and 10PM schedule. The typical home health agency nurse, not certified in Infusion Services, does not understand the importance of pharmacokinetics like the Coram nurses do. This situation impacted my patient. Having Coram licensed to provide nursing in conjunction with the infusion would have improved this patient's outcome. This example is not in insolation; I regularly have other such circumstances.

Again, please authorize Coram to provide skilled nursing services to meet the unique needs of infusion patients. Thank you.

Sincerely,

Margarita LaMothe, MD

The second of th



October 9, 2013

Ms. Melanie Hill Certificate of Need Program c/o Coram Alternate Site Services, Inc.

Dear Ms. Hill:

I am the Regional Nurse Manager with Coram Alternate Site Services, Inc. We recently had a patient Mrs. B. H. whose husband, Mr. H., was her primary caregiver. Mrs. B.H. was a terminal patient who has since expired. We met Mrs. B. H. while a patient in a local hospital. The hospital had arranged for Coram to provide Mrs. B. H. with the infusion products and a home health agency to provide the at home skilled infusion services. Upon accepting the patient, Coram nurses saw the patient in the hospital, doing the pump connection and line assessment as is the standard of care for this type of patient. Mrs. B. H. then went home.

One of Coram's standard protocols is conduct a 24 hour follow up by telephone with each patient. During this callback the day after doing the pump connection and line assessment, the family answered the telephone. They informed the Coram representative that the contracted home health agency was still there and having difficulty accessing the port. In fact, we were informed that two nurses had attempted with three different needles. Obviously, both Mrs. B. H. and Mr. H. were quite concerned and fearful of the circumstance.

In response, Coram nurses took additional supplies to the patient home and provided one on one education on the spot for the nursing agency nurse. Our Coram staff talked the nurse through the appropriate technique for successfully accessing the port. The situation was very unfortunate for Mr. and Mrs. H. Their encounter with the healthcare system was suboptimal and the level of care received was below acceptable quality.

Had Coram been licensed to provide this level of skilled care for this unique infusion patient type, there would have been many benefits to the patient and healthcare system in general. The patient would have had improved patient experience; the patient would not have had two nurses with three different needles; the patient's outcome would have been better; the patient would have received treatment consistent with the standard of care; the patient would have had less stressors in this circumstance although we do not know the ultimate impact of that improvement on the health and longevity of the patient.

From a general healthcare perspective, had Coram provided the service from the outset, it would have been more cost effective as Coram came to the patient home to educate the other home health agency on treatment methods – so now extra nurse skills were used to treat the patient; quality of care would have been improved as a result of eliminating the failed attempts to access the port; and patient experience with the healthcare system would have been improved.

It is circumstances like this that necessitate the need for Coram to have its certificate of need application to provide limited scope home health services be approved. Please give our request favorable consideration.

Thank you,

1 ficale His July Ben

Regional Nurse Manager



Pedlatric. Adolescent & Adult Care

Regional / Children's 2121 Highland Ave. Knoxville, TN 37916 1: (865) 525-2640 f: (865) 525-9536 info@allergyaa.com

West / Cedar Bluff 9017 Cross Park Drive Suite 100 Knoxville, TN 37923 (805) 693-4556

Emory Road / Conner Pointe 1 7714 Conner Road Suite 108 Powell, TN 37849 (865) 938-7759

Maryville / **Armory Place** 123 (iil) Street Alcoa, TN 37701 (865) 977-8242

Sevierville / Bradford Square 632 Dolly Parton Pkwy. Suite 5 Sevierville, TN 37862 (865) 429-9070

Morristown / Hamblen 500 McFarland Street Suite E Morristown, TN 37814 (423) 254-3590

Oak Ridge 1000 Oak Ridge Tumpike Oak Ridge, TN 37830

North / Fountain City Shot Office Only 4450 Walker Blvd Knoaville, TN 37917 (865) 689-7363

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Allergy & Asthma Affiliates

Donald T. Ellenburg, M.D. Timothy C. Frazier, D.Ph., M.D. Andrew M. Singer, M.D. W. Scout Robinson, M.D.

March 11, 2014

Ms. Melanie Hill Certificate of Need Program C/O Coram Alternate Site Services, Inc.

Dear Ms. Hill:

My name is Timothy Frazier, M.D.. I am board certified in allergy and immunology. My fellowship training was in both internal medicine and pediatrics. My practice consists of seeing both children and adults. My practice group currently has seven offices which are located in five different counties in the Greater Knoxville Area.

I have in the past referred many patients to Coram for specialty infusion services. Typically, the patients I am referring carry the diagnosis of primary immune deficiency. As you can understand, it is in general in the patient's best interest, with hypogammaglobulinemia, to avoid hospital settings and sick contacts. An ideal approach is for these patients to have treatments provided in the home when possible. Unfortunately, it is rare to find a home health agency willing to provide these services in the home, especially for pediatric patients. It is even a more difficult problem to find a home health agency willing to provide infusion nursing services for specialized infusion products such as IVIG, typically due to the lack of qualified nursing or inexperience in dealing with patients carrying diagnoses of primary immune deficiency.

I am well aware of the importance of Coram's role in the home health care of highly acute patients or patients at risk of contracting infection from sick contacts. It would be important to me, and more importantly my patients, that Coram's requested Certificate of Need be approved to established a limited home health agency in the East Tennessee Area specifically to provide services for patients such as these. These services would certainly improve my patients' quality of care and outcomes. As stated, I have dealt with Coram often in the past; and the need for skilled nursing services for this population of patients is a current great need that is inadequately met.

Due to the above, I am in support of seeing the Coram Company establish a home health agency here in the Knoxville area.

Sincerely,

Timothy C. Frazier, DPH, M.D.

TCF/dw

Board Certified by the American Board of Allergy & Immunology A conjoint Board of the American Board of Internal Medicine and the American Board of Pediatrics

SUBROTO KUNDU, M.D. East TN Neurology LLC

February 24, 2014

Ms. Melanie Hill Certificate of Need Program c/o Coram Alternate Site Services, Inc.

Dear Ms. Hill:

I am a neurologist in clinical practice, in East Tennessee, with offices in Cleveland and in Chattanooga. I am board certified by the Neurology division of the American Board of Psychiatry and Neurology (ABPN) (1990).

I am writing to you because my patients who require immunoglobulin therapy do not have adequate services available to them in East Tennessee, particularly in Cleveland. My experience is consistent. When my patients who require IVIG therapy, and the most appropriate quality of care site to administer is in the home, the availability of this service is virtually non-existent. The licensed home health agencies serving our area are not proficient in IVIG therapy, are not familiar with first dose protocols and are generally not available to provide a nursing visit that lasts five to six hours which my patients require.

For the good of my patients care, please approve Coram's requested home health agency certificate of need to provide skilled nursing related to infusion therapy in the home. I am confident that this will improve the quality of care delivery in our area and for my patients.

Thank you,

Subroto Kundu, MD



Pediatric, Adolescent & Adult Care

Regional / Children's 2121 Highland Ave. Knoxville, TN 37916 t: (865) 525-2640 f: (865) 525-9536

info@allergyza.com

West / Cedar Bluff 9017 Cross Park Drive State 100 Knoovalle, TN 37921 (865) 693-4556

Emory Road / Conner Pointe I 7714 Conner Road Sune 108 Powell, TN 37849 (865) 938-7759

Maryville / Armory Place 123 Gill Street Alcout, TN 37701 (868) 977-8242

Sevierville / Bradford Square 632 Dolly Parton Pawy, Suite 5 Sevierville, TN 37862 (865) 429-9070

Morristown / Hamblen 500 McFarland Street Suite E Morristown, TN 37814 (423) 254-3590

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Donald T. Ellenburg, M.D. Timothy C. Frazier, D.Ph., M.D. Andrew M. Singer, M.D. W. Scout Robinson, M.D.

February 27, 2014

To Whom It May Concern:

As an allergist and immunologist, I take care of several patients who have immune deficiency and need infusions. With recent changes in healthcare environment, insurance companies are pushing for infusions to be done at home; and we do have a shortage locally of trained nursing agencies which are able to infuse patients safely at home.

With this in mind, I please request Coram be approved for having a group of nurses who can do infusions at home to facilitate treatment of our patients.

Thank you for taking this into consideration.

Sincerely,

Andrew M. Singer, M.D.

AMS/dw

02/18/2014 11:02

From: CORAM HEALTHCARE

Phyllis Gibb 905 29th Street SE Cleveland, Tennessee 37323

December 4, 2013

Ms. Melanie Hill Certificate of Need Program c/o Coram Alternate Site Services, Inc.

Dear Ms. Hill:

I am a patient who has had a need for home infusion of intravenous immunoglobulininfusion (IVIG) therapy. Coram Specialty Infusion Services provides me with the products necessary for my treatment.

My treatment was five days per week, five to six hours per treatment for three weeks. No home health agency would provide the staffing support for me to have this treatment at home. Reasons they could not provide the staff was the duration and frequency of treatment.

I was forced to go to an infusion center which was time consuming, exposed me to germs and cost more for the care. In times when we should be concerned about cost effectiveness of care, quality of care and appropriateness of treatment by venue, my situation exemplifies what is wrong with the system.

Had Coram been able to provide the nursing staff support in my home and train me to selfadminister, outcomes, cost effectiveness and quality would have been improved.

It is important to me and others like me that you approve the Coram request to establish a limited service home health agency to serve the specialized needs of patients like me. Thank you very much for your consideration.

ATTACHMENT, SECTION C, ECONOMIC FEASIBILITY, ITEM 2

CORAM ALTERNATE SITE SERVICES, INC. FUNDING LETTER



May 31, 2014

Ms. Melanie Hill Executive Director Tennessee Health Services and Development Agency 500 Deaderick Street Nashville, Tennessee 37243

RE: Certificate of Need Application by Coram Alternate Site Services, Inc.

Establishment of a Limited Service Home Health Agency In West Tennessee (Memphis)

Dear Ms. Hill:

Coram Alternate Site Services, Inc. is filing the Certificate of Need (CON) application described above to become approved in 25 counties throughout West Tennessee. Coram Alternate Site Services, Inc. is a wholly owned subsidiary of Coram Specialty Infusion Services, Inc. which owns 100 percent of the Applicant's issued shares. Coram LLC is a parent of Coram Specialty Infusion Services and its ultimate parent is CVS Caremark Corporation (CVS). I hereby make the following funding commitment to Coram Alternate Site Services, Inc. on behalf of CVS for the purpose of establishing, licensing and operating the proposed limited service home health agency in West Tennessee.

The project costs identified on the Project Cost Chart in the CON application are \$98,000. CVS Caremark Corporation will fund these costs from its existing current assets (cash on hand). As the most recent 10Q of CVS indicates, CVS has in excess of \$2.7 billion cash and cash equivalents on hand as of March 31, 2014.

In addition to the commitment for the above noted project costs, CVS is also committed to providing the necessary working capital for this proposed home health agency as well as funding any operating deficits and other pre-opening costs. CVS has sufficient resources to fully fund these expenditures in addition to its other ongoing obligations. This is evidenced by CVS' balance sheet which is included as an attachment within the CON application.

Please accept this letter as confirmation of CVS Caremark Corporation's commitment to fund the proposed project including the total project costs, any necessary working capital, and any operating deficits incurred in the start up through its ongoing operation. We are fully committed to the funding of this project and look forward to the successful implementation of this program.

Thank you for your consideration.

MANNA

Sincerely

Senior Vice President, General Counsel & Secretary

Coram Alternate Site Services, Inc.

Morningstar® Document Research™

Form 10-Q

CVS CAREMARK CORP - CVS

Filed: May 02, 2014 (period: March 31, 2014)

Quarterly report with a continuing view of a company's financial position

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Table of Contents

10-Q - 10-Q

PART I

Item 1. Financial Statements

Part I

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

Part II

Item 1. Legal Proceedings

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Item 6. Exhibits

Signatures:

EX-15.1 (LETTER RE: UNAUDITED INTERIM FINANCIAL INFORMATION)

EX-31.1 (CERTIFICATION OF CEO PURSUANT TO SECTION 302 OF THE SARBANES -OXLEY ACT OF 2002)

EX-31.2 (CERTIFICATION OF CFO PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002)

EX-32.1 (CERTIFICATION OF CEO PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)

EX-32.2 (CERTIFICATION OF CFO PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

	FORM 10-Q	
	T PURSUANT TO SECTION 13 OR 15(d)	OF THE SECURITIES EXCHANGE ACT
OF 1934	For the Quarterly Period Ended March	31, 2014
☐ TRANSITION REPORT OF 1934	PURSUANT TO SECTION 13 OR 15(d) (OF THE SECURITIES EXCHANGE ACT
	For the transition period fromt	0
	Commission File Number 001-0	1011
(CVS CAREMARK CORPO	
Delaware (State of Incorporation)		05-0494040 (I.R.S. Employer Identification Number)
	One CVS Drive, Woonsocket, Rhode Is (Address of principal executive offices)	
Re	egistrant's telephone number, including area co	de: (401) 765-1500
Exchange Act of 1934 during th	ether the registrant (1) has filed all reports required e preceding 12 months (or for such shorter period t filing requirements for the past 90 days. Yes[X] No	hat the registrant was required to file such reports),
Interactive Data File required to	ether the registrant has submitted electronically and be submitted and posted pursuant to Rule 405 of R h shorter period that the registrant was required to s	egulation S-T (§232.405 of this chapter) during the
	ether the registrant is a large accelerated filer, an accinitions of "large accelerated filer," "accelerated filer,"	
Large accelerated filer [X]		Accelerated filer []
Non-accelerated filer [] (Do 1	not check if a smaller reporting company)	Smaller reporting company []
Indicate by check mark wh	ether the registrant is a shell company (as defined in	n Rule 12b-2 of the Exchange Act). Yes [] No [X]
Co	ommon Stock, \$0.01 par value, issued and outstand	ing at April 25, 2014:
	1,169,230,063 shares	
,		**************************************

1NDEX

		Page
Part I		
Item 1.	Financial Statements	
ie.	Condensed Consolidated Statements of Income (Unaudited) - Three Months Ended March 31, 2014 and 2013	<u>3</u>
	Condensed Consolidated Statements of Comprehensive Income (Unaudited) - Three Months Ended March 31, 2014 and 2013	<u>4</u>
	Condensed Consolidated Balance Sheets (Unaudited) - As of March 31, 2014 and December 31, 2013	<u>5</u>
	Condensed Consolidated Statements of Cash Flows (Unaudited) - Three Months Ended March 31, 2014 and 2013	<u>6</u>
	Notes to Condensed Consolidated Financial Statements (Unaudited)	<u>7</u>
	Report of Independent Registered Public Accounting Firm	<u>16</u>
Item 2. Item 3. Item 4.	Management's Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosures About Market Risk Controls and Procedures	17 28 28
Part II		
Item 1.	<u>Legal Proceedings</u>	<u>29</u>
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	<u>29</u>
Item 6.	Exhibits	<u>30</u>
Signatures		<u>31</u>

CVS Caremark Corporation Condensed Consolidated Statements of Income (Unaudited)

		Three Months Ended March 31,				
In millions, except per share amounts		2014		2013		
Net revenues	\$	32,689	\$	30,751		
Cost of revenues		26,747		25,174		
Gross profit	-	5,942		5,577		
Operating expenses	9	3,918		3,883		
Operating profit		2,024		1,694		
Interest expense, net		158		126		
Income before income tax provision	N=====	1,866	10	1,568		
Income tax provision		737		614		
Net income	\$	1,129	\$	954		
Net income per share: Basic						
Diluted	\$	0.96	\$	0.77		
Weighted averages shares outstanding: Basic	\$	0.95	\$	0.77		
Diluted		1,180		1,232		
		1,190		1,241		
Dividends declared per share	\$	0.275	\$	0.225		
See accompanying notes to condensed consolidated financial statements.				2		

3

181 CVS Caremark Corporation Condensed Consolidated Statements of Comprehensive Income (Unaudited)

	Th	ree Months	Ended M	Iarch 31,
In millions		2014	3-	2013
Net income	\$	1,129	\$	954
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax		9		(2)
Cash flow hedges, net of tax		1		1
Total other comprehensive income (loss)	,	10		(1)
Comprehensive income	\$	1,139	\$	953

See accompanying notes to condensed consolidated financial statements.

1

182 CVS Caremark Corporation Condensed Consolidated Balance Sheets (Unaudited)

In millions, except per share amounts	-	March 31, 2014	I	December 31, 2013
Assets: Cash and cash equivalents	\$	2,766	¢	4.000
Short-term investments	Ф		\$	4,089
Accounts receivable, net		82		88
Inventories		9,086		8,729
Deferred income taxes		11,188		11,045
Other current assets		929		902
Total current assets	_	409		472
Property and equipment, net		24,460		25,325
Goodwill		8,676		8,615
Intangible assets, net		28,139		26,542
Other assets		9,986		9,529
Total assets		1,561		1,515
1 Out about	\$	72,822	\$	71,526
Liabilities: Accounts payable				
Claims and discounts payable	\$	5,638	\$	5,548
Accrued expenses		4,878		4,548
Current portion of long-term debt		5,132		4,768
Total current liabilities	-	565		561
Long-term debt		16,213		15,425
Deferred income taxes		12,845		12,841
		4,053		3,901
Other long-term liabilities		1,499		1,421
Commitments and contingencies (Note 9)				-
Shareholders' equity: CVS Caremark shareholders' equity: Preferred stock, par value \$0.01: 0.1 share authorized; none issued or outstanding Common stock, par value \$0.01: 3,200 shares authorized; 1,684 shares issued and 1,173		_		

shares outstanding at March 31, 2014 and 1,680 shares issued and 1,180 shares 183 outstanding at December 31, 2013	17	17
Treasury stock, at cost: 510 shares at March 31, 2014 and 500 shares at December 31,	17	17
2013	(20,919)	(20,169)
Shares held in trust: 1 share at March 31, 2014 and December 31, 2013	(31)	(31)
Capital surplus	29,985	29,777
Retained earnings	29,297	28,493
Accumulated other comprehensive loss	(139)	(149)
Total CVS Caremark shareholders' equity	38,210	37,938
Noncontrolling interest	2	<u> </u>
Total shareholders' equity	38,212	37,938
Total liabilities and shareholders' equity	\$ 72,822	\$ 71,526

See accompanying notes to condensed consolidated financial statements.

5

ATTACHMENT, SECTION C, ECONOMIC FEASIBILITY, ITEM 4

CORAM ALTERNATE SITE SERVICES, INC.

FORECASTED UTILIZATION AND FINANCIAL PERFORMANCE – EXISTING LICENSED PHARMACY

PROJECTED DATA CHART -- EXISTING MEMPHIS OPERATIONS

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in: January (month) BUDGET BEFORE PROJECT Year Year One Year Two Infusion Patients A Utilization Data Patients 911 1,002 Infusion Pt Months 1,804 Patient Months 1,984 Patients Home Health Patients 0 0 Nursing Visits Home Health RN Visits 0 0 B Revenue from Services to Patients 1 Inpatient Services 2 Outpatient Services \$6,813,292 \$6,193,902 **Emergency Services** Other Operating Revenue Gross Operating Revenue \$6,193,902 \$6,813,292 C Deductions from Gross Operating Revenue 1 Contractual Adjustments 2 Provsion for Charity Care \$61,326 \$67,459 3 Provisions for Bad Debt \$184,558 \$203,014 **Total Deductions** \$245,884 \$270,472 NET OPERATING REVENUE \$5,948,018 \$6,542,820 D Operating Expenses 1 Salaries and Wages \$1,433,675 \$1,548,369 \$197,063 \$132,456 Benefits Physician Salaries and Wages \$27,779 \$30,001 3 Supplies Taxes \$17,810 \$19,235 Depreciation \$12,827 \$13,853 5 \$106,880 \$111,155 6 Rent Interest, Other than Capital \$0 \$0 Management Fees: a. Fees to Affiliates \$0 \$0 b. Fees to Non-Affiliates \$0 \$0 P Other Expenses Specify in chart \$4,059,470 \$4,462,135 **Total Operating Expenses** \$5,840,907 \$6,381,812 E Other Revenue (Expenses - Net (Specify) **NET OPERATING INCOME (LOSS)** \$107,111 \$161,008 F Capital Expenditures 1 Retirement of Principal 2 Interest Total Capital Expenditures \$0 \$0 NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES \$107,111 \$161,008 Attachment

PROJECTED DATA CHART - OTHER EXPENSES

OTHER EXPENSE CATEGORIES

1	Drugs/Materials	\$3,809,993	\$4,190,992
2	Shipping/Delivery	\$85,396	\$93,936
3	Travel/Lodging	\$32,031	\$34,593
4	Operational Costs: Utilities, Telephone, Professional Fees, and Other Adminstrative Costs	\$132,050	\$142,614
6			

Total Other Expenses

\$4,059,470 \$4,462,135

Attchment

PROJECTED DATA CHART --EXISTING BUSINESS PLUS NEW BUSINESS WEST TENNESSEE (MEMPHIS BRANCH)

WEST TENNESSEE (MEMPHIS BRANCH)

Give information for the two
The fiscal year begins in:

January (month)

	1100	aryour begins in.		
Yea	ar		Year One	Year Two
Α	Utili	Patients Infusion Patients Patient Months Patients Home Health Patients Nursing Visits Home Health RN Visits	911 1,804 207 1,775	1,002 1,984 228 1,952
В	Rev 1	enue from Services to Patients Inpatient Services	\$0	\$0
	2	Outpatient Services	\$6,459,445	\$7,119,995
	3	Emergency Services	\$0	\$0
	4	Other Operating Revenue	\$0	\$0
	Gro	ss Operating Revenue	\$6,459,445	\$7,119,995
С	Ded 1	uctions from Gross Operating Revenue Contractual Adjustments	\$10,622	\$12,268
	2	Provsion for Charity Care	5741608	New TY
	3	Provisions for Bad Debt	3)89(6)	<u> </u>
	Tota	I Deductions	\$275,094	\$304,210
ΝE	т ор	ERATING REVENUE	\$6,184,351	\$6,815,785
D		rating Expenses Salaries and Wages Benefits Physician Salaries and Wages	\$1,593,715 \$214,474 \$0	\$1,729,694 \$233,328 \$0
	3	Supplies	\$34,878	\$37,811
	4	Taxes	\$17,810	\$19,235
	5	Depreciation	\$12,827	\$13,853
	6	Rent	\$ 106,880	
	7	Interest, Other than Capital	F1 (30)	
	8	Management Fees: a. Fees to Affiliates b. Fees to Non-Affiliates	\$0 \$0	\$0 \$0
	Р	Other Expenses Specify in chart	\$4,096,174	\$4,505,087
	Tota	Operating Expenses	\$6,076,758	\$6,650,163
Ε	Othe	r Revenue (Expenses - Net (Specify)		
ΝEΊ	ГОР	ERATING INCOME (LOSS)	\$ 07,593	\$165,622
F	Cap 1	tal Expenditures Retirement of Principal		
	2	Interest	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	75.15
	Tota	Capital Expenditures	\$0	\$0
NET	OP	ERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$107,593	\$165,622 Attachment
			-	

PROJECTED DATA CHART - OTHER EXPENSES

OTHER EXPENSE CATEGORIES

1	Drugs/Materials	\$3,809,993	\$4,190.99
2	Shipping/Delivery	\$85,396	\$93.93
3	Travel/Lodging	\$32,031	\$34.59
4	Operational Costs: Utilities, Telephone, Professional Fees, and Other	\$132,050	\$142,61
5	Mileage	\$36,704	\$42.95
6			

Total Other Expenses

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Attachment

ATTACHMENT, SECTION C, CONTRIBUTION TO ORDERLY DEVELOPMENT, ITEM 7(b)

CORAM ALTERNATE SITE SERVICES, INC. JOINT COMMISSION LETTER



August 5, 2013

Ruth Ann Ellison Vice President Clinical Regulatory Compliance Apria Healthcare, Inc 26220 Enterprise Court Lake Forest, California 92630

HCO ID: #439173

Dear Ms. Ellison:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Accredited for all services surveyed under the applicable manual noted below:

Comprehensive Accreditation Manual for Home Care

This accreditation cycle is effective beginning May 11, 2013. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 36 months.

Services provided by your organization: Home Health, Ambulatory Infusion, Pharmacy Dispensing, and/or Clinical Consultant Pharmacist Services.

Sites accredited:

Coram Healthcare Corporation of Alabama, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 300 Riverhills Business Park Suite 390, Birmingham, AL 35242

Coram Alternate Site Services, Inc., 1519 S Bowman Road Suite C, Little Rock, AR 72211

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 4310 East Cotton Center Blvd Suite 110, Phoenix, AZ 85040

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 6375 East Tanque Verde Road Suite 50, Tucson, AZ 85715

Kern Home Health Resources dba Coram Healthcare, 3101 Sillect Avenue Suite 109, Bakersfield, CA 93308

Coram Healthcare Corporation of Southern California, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 5571 Ekwill Street Suite A- B, Goleta, CA 93111

Coram Healthcare Corporation of Northern California, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 3160 Corporate Place, Hayward, CA 94545

Coram Healthcare Corporation of Southern California, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2710 Media Center Drive Bldg #6 Ste 150, Los Angeles, CA 90065

Coram Healthcare Corporation of Southern California, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 4355 East Lowell Street Suite C. Ontario, CA 91761

www.jointcommission.org

Headquarters
One Renaissance Boulevard

Oakbrook Terrace, IL 60181 630 792 5000 Voice



Coram Healthcare Corporation of Northern California, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 9332 Tech Center Drive Suite 100, Sacramento, CA 95826

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 12310 World Trade Drive Suite 100, San Diego, CA 92128

Coram Healthcare Corporation of Northern California, dba Coram Specialty Infusion Services, an Apria Healthcare Company 1635 Divisadero Suite 135 San Francisco, CA 94115

Coram Healthcare Corporation of Southern California, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 3002 Dow Avenue Suite 104, Tustin, CA 92780

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 12450 East Arapahoe Road Suite A1, Centennial, CO 80112

Coram Clinical Trials, Inc., 555 17th Street Suite 1500, Denver, CO 80202

Coram LLC 555 17th Street Suite 1500, Denver, CO 80202

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2 Barnes Industrial Park Road South Suite A, Wallingford, CT 06492

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 9143 Philips Highway Suite 300, Jacksonville, FL 32256

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 555 Winderley Place Suite 300, Maitland, FL 32751

Coram Healthcare Corporation of Southern Florida, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 11948-50 Miramar Parkway, Miramar, FL 33025

Coram Healthcare Corporation of Florida, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 8508 Benjamin Road Suite C Tampa, FL 33634

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 3416 Jenks Avenue Suite A, Panama City, FL 32405

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 3439 North 12th Avenue Suite A & B, Pensacola, FL 32503

Coram Alternate Site Services, Inc. dba Coram Specialty Infusion Services, an Apria Healthcare Company, 1 NE 1st Avenue Suite 202, Ocala, FL 34470

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2140 New Market Parkway Suite 106, Marietta, GA 30067

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 3513 Vine Court, Davenport, IA 52806

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 11660 West Executive Drive, Boise, ID 83713

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2022 Glen Park Drive, Champaign, IL 61821

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 1471 Business Center Drive Suite 500, Mount Prospect, IL 60056

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 11711 North College Avenue Suite 125, Carmel, IN 46032-5601

Coram Healthcare Corporation of Indiana, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 1290 Arrowhead Court Suite A, Crown Point, IN 46307

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 431 Fernhill Avenue, Fort Wayne, IN 46805

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 8013 Flint Street, Lenexa, KS 66214

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 8201 East 34th Street Circle North Suite 905, Wichita, KS 67226

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 115 James Drive West Suite 100, St. Rose, LA 70087

Coram Healthcare Corporation of Massachusetts, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 575 University Avenue Suite 2, Norwood, MA 02062

Coram Healthcare Corporation of Greater D.C., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 7150 Columbia Gateway Drive Suite E, Columbia, MD 21046



Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 12 Northbrook Drive, Building B, Suite #1, Falmouth, ME 04105

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 4334 Brockton Drive SE Suite D, Kentwood, MI 49512

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 28550 Cabot Drive Suite 200, Novi, MI 48377

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2345 Waters Drive, Mendota Heights, MN 55120

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services an Apria Healthcare Company, 2901 Frontage Road South 10 Highway East Suite 7, Moorhead, MN 56560

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2900 Falling Leaf Lane Suite 101, Columbia, MO 65201

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 8248 Lackland Road Suite 101, St Louis, MO 63114

Coram Healthcare Corporation of Mississippi, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2929 Layfair Drive Suite 100, Flowood, MS 39232

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 30 Garfield Street Suite B, Asheville, NC 28803

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 9401-J Southern Pine Blvd, Charlotte, NC 28273

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 507 Airport Blvd Suite 100, Morrisville, NC 27560

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 11111 Mill Valley Road, Omaha, NE 68154

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 11 H Commerce Way, Totowa, NJ 07512

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 7400 Washington Street NE, Albuquerque, NM 87109

Coram Healthcare Corporation of Nevada, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 1951 Ramrod Avenue Suite 110, Henderson, NV 89014

Coram Healthcare Corporation of Nevada, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 101 North Pecos Road Suite 106, Las Vegas, NV 89101

Coram Healthcare Corporation of Nevada, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 6490 South McCarran Blvd Suite 29, Reno, NV 89509

Coram Healthcare Corporation of Greater New York, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 12 Jupiter Lane, Albany, NY 12205 Coram Healthcare Corporation of Greater New York, dba Coram Specialty Infusion Services, an Apria

Healthcare Company, 375 North French Road Suite 108, Amherst, NY 14228 Coram Healthcare Corporation of Greater New York, dba Coram Specialty Infusion Services, an Apria

Healthcare Company, 744 Ulster Avenue Suite #1, Kingston, NY 12401
Coram Healthcare Corporation of Greater New York, 45 South Service Road, Plainview, NY 11803

Coram Healthcare Corporation of Greater New York, 97 -77 Queens Blvd Suite 1100, Rego Park, NY 11374

Coram Healthcare Corporation of Greater New York, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2949 Erie Blvd East Suite 103, Syracuse, NY 13224

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 4060 Business Park Drive Suite 101, Columbus, OH 43204-5023

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 4305 Mulhauser Road Suite 1, Fairfield, OH 45014

Coram Alternate Site Services, Inc., dba Toledo IV Care, 4060 Technology Drive, Maumee, OH 43537 Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 6565 Davis Industrial Parkway Suite AA, Solon, OH 44139

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 235 North MacArthur Boulevard Suite 100, Oklahoma City, OK 73127



Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 7358 SW Durham Road, Portland, OR 97224

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 220 Executive Drive Suite 500, Cranberry Township, PA 16066

CoramRX, LLC, 4 Spring Mill Drive, Malvern, PA 19355

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 6 Spring Mill Drive, Malvern, PA 19355

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 155 N Donnerville Rd Ste 1, Mountville, PA 17554

Coram Healthcare Corporation of Massachusetts, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 1240 Pawtucket Avenue, East Providence, RI 02916

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 5955 Core Ave Suite 512, North Charleston, SC 29406

Coram Healthcare/Carolina Home Therapeutics, 720 Gracern Road Suite 123, Columbia, SC 29210 Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 1828 Midpark Rd Ste D, Knoxville, TN 37921

Coram Alternate Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 1680 Century Center Parkway Suite 12, Memphis, TN 38134

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 2970 Sidco Drive, Nashville, TN 37204

Coram Alternate Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 1905-A Kramer Lane Suite 500, Austin, TX 78758

Coram Healthcare Corporation of North Texas, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 10105 Technology Blvd West Suite 102, Dallas, TX 75220

Coram Alternate Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 7365 Remcon Circle Suite A-102, El Paso, TX 79912

Coram Alternate Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 10611 South Sam Houston Parkway West Suite 200, Houston, TX 77071

Coram Alternate Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 10118 Huebner Road, San Antonio, TX 78240

Coram Healthcare Corporation of Utah, dba Coram Specialty Infusion Services, an Apria Healthcare Company, 120 West Vine Street Suite 140, Murray, UT 84107

Coram Healthcare Corporation of Greater D.C., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 4115 Pleasant Valley Road Suite 200, Chantilly, VA 20151

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 14935 NE 87th Street Suite 101, Redmond, WA 98052

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 720 Olive Way Suite 815, Seattle, WA 98101-1836

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 520 E. North Foothills Drive Suite 400, Spokane, WA 99207

Coram Alternate Site Services, Inc., dba Coram Specialty Infusion Services, an Apria Healthcare Company, 5345 South Moorland Road Suite 101, New Berlin, WI 53151

Please be assured that the Joint Commission will keep the report confidential, except as required by law. To ensure that the Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the Centers for Medicare and Medicaid Services (CMS), state or regional regulatory services, and the public you serve of your organization's accreditation decision. Please visit Quality Check® on the Joint Commission web site for updated information related to your accreditation decision.

www.jointcommission.org

Headquarters

One Renaissance Boulevard Oakbrook Terrace, 1L 60181 630 792 5000 Voice



If I can be of further assistance I can be reached at (630) 792-5732.

Sincerely,

Kenneth M. Gauss

Kenneth M. Gauss Senior Account Executive, Team 3 Accreditation and Certification Operations

cc: Correspondence File

ATTACHMENT, SECTION C, CONTRIBUTION TO ORDERLY DEVELOPMENT, ITEM 7(d)

CORAM ALTERNATE SITE SERVICES, INC.

MOST RECENT INSPECTION OF THE MEMPHIS BRANCH

PHARMACY STREET	1043 31(11205)			THE STATE OF THE S	TENNESSEE E COMMUN COMPLIA	MENT OF HEALTH BOARD OF PHARMACY NITY INSPECTION ANCE INSPECTION
CITY (pycli) (U (Pa Sef Y (A) U Sa	1	Inspected	i by	Plour En	Date
	78134		Sr.		Jenalouva	11-26-2011
DATE OPENED	TELEPHONE NO.		This Insp		Opening	☐ Relocation
	(901)326-3738		Satisfacto	OTV.	☐ New Ownership	
LICENSE NO _A	EXPIRY DATE				☐ Counseling Compli	☐ Follow-up ance
2051	6-30-2013		Yes 🛛 🚁	No LI	Periodic 19. RXs numerically fil	☐ Remodeling
DEA NO.	EXPIRY DATE				☐ All C's together □@f	s separate [] Multiple file method
1804445624	7 8-31-2014		l ligan of		20. Patients identifiable 21. Prescribers identifia	
PHARMACIST IN CHARGE/	Důty LIC NO. EXPIRY DATE				22. New verbal RXs ini	tialed by appropriate personnel
Susse Alman Wh	20 1155 83 7-317014				23. Date of original disp 24. Initials of dispensin	pensing
			400		25. Quantity dispensed	indicated
Compliance Yes No	PERSONNEL		2 34		 Appropriate Emerge Computer labels apr 	ancy C-11 RXs
	appropriate identification/Name Tags		10		28. Pharmacist Signatur	plied appropriately to RXs
). Ph./Tech ration ersonnel/apparel clean		1000		29. Daily Print Out	
[/4) T	ech registry & Affidavit	J	Compl	lance	DRUG PRODI	ICT SUBSTITUTION
Compliance		1	Yes	No	30. Authorization docum	
Yes No	PHYSICAL REQUIREMENTS		1		31. Manufacturer indica	
	ertificates Displayed X Dept. – Sufficient Space/Counseling				32. Approved products i	
7. F	ully enclosed when applicable		Compl	iance	DATTENT	COUNCENTRIC
<u>اس المنا</u> 8. K	ey Lockable/Key Control		Yes	No	device at the second of the second	COUNSELING
Compliance	DRUGS AND EQUIPMENT				 Patient profiles Drug Utilization Rev 	new
Yes No 9. D	rispensing area clean, orderly, well lighted	AH	grana. I		35. Patient Counseling	
10. S	ink, hot and cold water		Compli	ance	CONTROLLED	Uner Aven Necessae
	efrigeration eferences, periodicals		Yes	No		UBSTANCE RECORDS
13. V	ials and closures (child-proof)		12		 Readily retrievable All C-11 records sep 	arate
	helves and drug stock clean rugs in-date				38. DEA Form 222 Copy	y 3 on hand & completed
. 16. L	abels correct on repackaging		nger Jan		 Drug Receipt date or Record of drug transi 	
17. L	egend drugs stored in RX Dept. rringes/insulin, restricted products non-				41. Schedule V sales	record book
ac	cessible				☐ Methamphetan 42. Last DEA Inventory	nine Sales Log
	77		T.		42. Last Theft/loss repor	t (date)
Pharmacy Hours	√ 5		1000		43. Access to Control Su	ubstance Monitoring Database
TEMS TO BE CORRECT mediately eeds improvement ithin 30 Days		REQU	TRED	<u>Ars</u> Sala	YES 🗆	NO []
emarks or Recommendation		1-1 1-1 1-1	100d 111. 111.	1 ⁰ 055 L.T.E Cols	<u> 2007 27 27 27 27 27 27 27 27 27 27 27 27 27</u>	1212 L., Kordy D
janani i Mil	hereby acknow	ledge a	and under	stand al	I notations made on th	is report; and confirm that

Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

PII# 4031 Revised 07/08

SUPPLEMENTAL - #1 -Copy-

CORAM SPECIALTY INFUSION

CN1406-018



June 20, 2014 12:06 pm



333 commerce street, suite 1500 nashville, tennessee 37201 phone: 615.256.0500 fax: 615.251.1059

h3gm.com

June 20, 2014

VIA HAND DELIVERY

Phillip M. Earhart
HSD Examiner
State of Tennessee
Health Services and Development Agency
Andrew Jacskon Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re:

Certificate of Need Application CN1406-018

Applicant's Response to Request for Supplemental Information

Dear Mr. Earhart:

We are in receipt of the Agency's Request for Supplemental Information. Please accept this as the Applicant's response to the same. Mr. Dell's Affidavit is attached hereto as <u>Exhibit</u> A.

1. Section A, Applicant Profile, Item 4

The license provided for Coram Specialty Infusion Services in Attachment, Section A, Item 4.3 is noted. However, the license is out of date (expires January 30, 2014). Please provide a copy of an updated license.

Attached are the updated licenses for the Memphis pharmacy in Attachment to Question #1.

2. Section A, Applicant Profile, Item 6

The provided lease is noted. However, please provide a signed fourth amendment to the lease which extends the existing lease to June 30, 2015.

In box 6.C the applicant indicates the duration of the lease is 5 years. However, it appears the lease expires June 30, 2015. Please clarify.

Attached is an executed copy of the fourth amendment to the lease in Attachment to Question #2. The five years commenced in 2010 and end in 2015. The lease is extended every five years via renewals as demonstrated by the fact the current period is the fourth renewal. The Applicant intends

June 20, 2014 12:06 pm

on again renewing the lease in 2015 to extend the lease an additional five years in accordance with the lease terms.

3. Section A, Applicant Profile, Item 12 and 13

The applicant indicates in item 12 certification will not be sought for Medicare and/or Medicaid. However, in item 13 the applicant indicates this project involves the treatment the TennCare participants. Please clarify.

Why has the applicant decided not to provide in-home infusion services to TennCare/Medicare enrollees?

Please clarify if TennCare/Medicare enrollees will be provided infusion services as out-of-network or under some other arrangement.

If the applicant does not plan not to provide home health infusion nursing services to TennCare/Medicare enrollees, where would enrollees be referred for those services? If a home health provider is not located, would an enrollee be required to travel on-site for infusion services? Please be specific.

On page 29 the applicant has documented difficulties in meeting the infusion nursing needs of its infusion therapy patients. Do these difficulties only apply to non-TennCare and Medicare patients? Please clarify how a non-homebound patient who needed infusion services would receive those services.

Is the applicant's current Memphis licensed home infusion pharmacy only serving non-TennCare/Medicare patients?

Although the Applicant will not seek certification as a Medicare home health agency or enroll in TennCare it will on occasion treat Medicarecovered and TennCare covered infusion patients, and either bill the patient a self-pay rate private nursing visit, or, if the patient's qualify (which most TennCare patients do) apply the visit to the Applicant's charity care pool and bad debt policy. The vast majority of the Medicare/TennCare infusion patients that the Applicant will treat are not considered "home bound," a finding necessary to support billing those programs for home health services. The patient's infusion drugs and therapies are, however, covered by Medicare/TennCare and the Applicant's pharmacy bills those programs for those medications and therapies. The difficulties its patients and their primary care providers encounter in securing nursing services to support delivery of the infusion therapies in the home is not necessarily unique to Medicare/TennCare, but those programs do require the patient be considered home-bound in order to bill those programs. As a result, existing agencies typically will not see those patients because they cannot get paid. If the Applicant's CON is approved, it will see these non-home

SUPPLEMENTAL #1
June 20, 2014

12:06 pm

Phillip M. Earhart June 20, 2014 Page 3

bound patients, and bill them at our self-pay rates for the nursing service, or apply the visit to the Applicant's charity care or bad debt policy.

The Applicant's Memphis licensed home infusion pharmacy is serving TennCare, Medicare, TriCare, VA, Champus and commercial payors. The TennCare and Medicare services for which the pharmacy has a provider number will continue to be by the pharmacy, even after the limited service home health agency is operational.

4. Section B, Project Description, Item I

The applicant is proposing to add one full time RN to provide home health infusion services to 207 patients representing 1,775 RN visits in Year One. Please clarify how this is possible.

On page 95 of the application, the applicant projects 1.95 RN FTEs in Year One. If necessary, please revise.

Please provide an overview of how home health infusion staff will be distributed in the 25 proposed counties.

Please clarify the relationship between Coram and Apria Healthcare.

If approved, please clarify if the applicant will subcontract any home health services associated with this application.

What are the risks of a patient experiencing a reaction to a medication as a result of a first dose administered by a home health agency in the home?

If a patient is new, typically are the first infusion doses administered in a controlled setting such as a hospital, MD office, clinic, etc.?

Based on the estimated number of nursing hours required for the 207 patients, there is budgeted 1.95 full-time equivalent RNs for Year One. These nurses will provide 4,060 hours of nursing care during that period. The nursing will be provided from a pool of 8 to 15 nurses located throughout the region. It is anticipated that one of these 8 to 15 nurses will be a full time nurse and will be supplemented by numerous hourly/pool staff located throughout West Tennessee. Staffing will be adjusted and needs met based on patient locations throughout the West Tennessee Service Area.

The typical length of a home health visit is 1 or so hours for non-specialty patients and 3 to 5 or 6 hours for specialty patients. Some of the specialty patients require their visits for their entire lives, and are not short-term patients.

June 20, 2014 12:06 pm

Coram was previously/formerly an indirect subsidiary of Apria Healthcare. On January 16, 2014, an affiliate of CVS Caremark Corporation acquired 100 percent of the voting interests of Coram LLC and its subsidiaries (collectively, "Coram"), the specialty infusion services and enteral nutrition business unit of Apria Healthcare Group Inc. Thereby, as of January 16, 2014 Apria Healthcare Group, Inc, and its operating subsidiary, Apria Healthcare, LLC have no ownership rights or affiliation with Coram, neither operationally nor structurally. Please refer to the Organizational Chart in the CON Application. Any reference to Apria in CN1406-017 should be deleted.

The Project Chart identifies services provided by all nursing staff (pool and employees) based on hours of care and number of patients. If necessary, some of these services may be subcontracted but that is not the intent at this time as the limited service agency is designed to treat patients the other home health agencies will not accept.

- Coram has a specific First-Dose Policy, which includes specific risk assessments and procedures for implementation. A copy of the First Dose Policy is included herein at Attachment to Question #4. Coram's First Dose Policy describes the guidelines for administration of the first dose of a medication in the home. The nurse and pharmacist shall review patient specific information in conjunction with the physician, prior to approving the administration of the first dose of a medication in the home. Prior to the administration of a first dose, the potential for risk and adverse reactions is assessed. If there is increased risk of adverse reaction, the first dose is administered in a controlled medical environment, (i.e., hospital, physician's office or clinic, emergency room or Ambulatory Infusion Suite). In the event the patient is administered in the home and there is an adverse reaction, the nurse shall stay with the patient until the patient is stable or care has been transferred to an emergency care Additional requirements for first dose administration in the provider. home: back-up emergency services (911 service or ambulance availability); access to working telephone; availability of referring physician (via telephone); availability of caregiver (must be present); and signed acute infusion reaction orders. There are certain medications that Coram does not administer as a first dose in the home. Additionally, there are specific procedures the clinician must follow relative to Coram's First Dose Policy as detailed in the attached Policy.
- 5. Section B, Project Description, Item III (Plot Plan)

The plot plan is noted. Please provide a plot plan that indicates size of the site (in acres).

Attached is an updated plot plan indicating the number of acres at 5.80 acres (See Attachment to Question #5).

June 20, 2014 12:06 pm

6. Section B, Project Description, Item V (Home Health Agency)

Does the applicant propose any branch offices?

The Applicant does not propose any branch offices.

- 7. Section C, Need, Item 1., 5 Principals for Achieving Better Health
 - 1. Improve the Health of Tennessee

The applicant states patients will be trained in self-care and administration. Please discuss what is included in self-care and administration of infusion products and services. Please describe the oversight that will be provided by the applicant in this arrangement.

Self-care and administration indicates the patient (and/or caregiver) fully understands the patient plan of care and has mastered proficiency for performing and managing the prescribed therapy. When it becomes apparent that the patient or caregiver requires further education or when a new or existing caregiver requires further instruction, Coram is aware of this almost immediately due to its oversight of the patient and its clinical nursing team who work on the pharmacy (not home health) side of the business.

Coram adopts a specific policy to describe the patient education process to ensure that patients/caregivers receive training and education in a manner that meets their language, reading and comprehension needs. Patients admitted to service shall receive Coram educational materials pertinent to the therapy prescribed, administration procedures and self-care instructions. Patient education and teaching documentation is audited as part of the clinical chart audit on a routine basis. Patient education tools shall be reviewed at least annually and updated to maintain current standards.

Patients and/or their caregiver(s) are assessed prior to initiating the educational process for their ability to comprehend the teaching tools provided. This assessment includes the patient and/or caregiver's readiness to learn, barriers to learning, cultural and spiritual practices and language barriers that may require a revised approach to patient education. As part of this process age, culture, language, physical impairment, literacy, education method, cognitive alertness, emotional state, motivation and knowledge are considered.

June 20, 2014 12:06 pm

The education of self-care and administration begins upon admission to service. Patient education and teaching is ongoing, based upon the patient assessment and compliance with the plan of care, response to therapy and proficiency for performing and managing the prescribed therapy. Ongoing patient education is provided any time the therapy regimen or self-administration procedures change, when it becomes apparent that the patient or caregiver requires further education or when a new or existing caregiver requires further instruction. For those patients who do not receive home nursing care from Coram nurses, education will be provided by an admissions clinician. Patients who have received therapy and access management instructions from the hospital clinical staff or physician's office prior to admission to Coram services and/or patients who have received home infusion services before, will have their competency verified. A Coram clinician will contact the patient or caregiver for a verbal review of the process to be performed.

2. Reasonable Access to Care for Every Citizen
The applicant plans to not serve TennCare/Medicare patients. Please indicate how this population will access this type of service.

Although the Applicant will not seek certification as a Medicare home health agency or enroll in TennCare it will on occasion treat Medicarecovered and TennCare covered infusion patients, and either bill the patient a self-pay rate private nursing visit, or, if the patient qualifies (which most TennCare patients do) apply the visit to the Applicant's charity care pool and bad debt policy. The vast majority of the Medicare/TennCare infusion patients that the Applicant will treat are not considered "home bound," a finding necessary to support billing those programs for home health services. The patient's infusion drugs and therapies are, however, covered by Medicare/TennCare and the Applicant's pharmacy bills those programs for those medications and therapies. The difficulties its patients and their primary care providers encounter in securing nursing services to support delivery of the infusion therapies in the home is not necessarily unique to Medicare/TennCare, but those programs do require the patient be considered home-bound in order to bill those programs. As a result, existing agencies typically will not see those patients because they cannot get paid. If the Applicant's CON is approved, it will see these non-home bound patients, and bill them at our self-pay rates for the nursing service, or apply the visit to the Applicant's charity care or bad debt policy.

8. Section C, Need, Item 1.a. (Project Specific Criteria-Home Health Services) (1.-4.)

June 20, 2014 12:06 pm

The applicant states engaging a local home health agency to provide the first dose in a lengthy ongoing infusion therapy session is difficult at best. Please discuss the reasons why this is so. Please describe a first dose policy.

The applicant provides a study of existing home health agencies in the proposed service area. Please provide the number of home health agencies polled, the response rate of those home health agencies contacted, the method (telephone, mail, etc.), and tool (interview, questionnaire, etc.) for each study area.

In conducting the service area home health studies on pages 33-45 of the application, did Coram reveal to the Home Health Agencies polled the data would be used to file for a home health certificate of need for infusion services?

Based on the data initially submitted in the application, the applicant has submitted information which shows a sizeable surplus of home health services to the projected need for CY 2018 in the each of the 25 counties and the service area as a whole. Please discuss why the applicant feels there is a need for an additional home health service agency at this time.

The chart of 2013 home health visits per 100 population by service area county on page 46 is noted. The chart reveals Decatur County has a rate of over 5 visits per 100 population more than any other home health agency in the proposed 25 county service area. What factors does the applicant see that attributes to Decatur County being an outlier in home health utilization?

Existing HHAs do not provide First Dose Therapies as a result of the fact they do not have policies in place to support safe administration of first lifetime dose. In contrast, Coram has a first dose policy that screens patients for safe administration of this first dose in the home.

Coram's First Dose Policy describes the guidelines for administration of the first dose of a medication in the home. The nurse and pharmacist shall review patient specific information in conjunction with the physician, prior to approving the administration of the first dose of a medication in the home. Prior to the administration of a first dose, the potential for risk and adverse reactions will be assessed. If there is increased risk of adverse reaction, the first dose is administered in a controlled medical environment, (i.e., hospital, physician's office or clinic, emergency room or Ambulatory Infusion Suite). If administered in the home, the nurse remains in the home for at least 30 minutes after the completion of a first dose infusion. If the first dose is a continuous infusion lasting more than one hour, the nurse shall stay for the first hour of that infusion. In the event that there is an adverse reaction, the nurse shall stay with the patient until the patient is stable or care has been transferred to an emergency care provider. Additional requirements for first dose administration in the home:

June 20, 2014 12:06 pm

back-up emergency services (911 service or ambulance availability); access to working telephone; availability of referring physician (via telephone); availability of caregiver (must be present); and signed acute infusion reaction orders. There are certain medications that Coram does not administer as a first dose in the home. Additionally, there are specific procedures the clinician must follow relative to Coram's First Dose Policy. The First Dose Policy is included in Attachment to Question #4.

Regarding the home health survey conducted, it was a telephonic poll of existing home health agencies. The caller identified herself as a Coram employee. Contact like this is not unusual, because Coram employees regularly contact area home health agencies to solicit home health agencies to support Coram pharmacy patients. The Coram representative did not mention the possibility that the Applicant would be filing a CON application.

There are 62 licensed agencies in West Tennessee, of which 61 admitted at least one patient during the past three years. However, some of these agencies have more than one branch office, resulting in more locations than the 62 licensed agencies. Attempts were made to contact all agencies. Forty-six agencies provided responses, representing a 75 percent participation level. The numbers and percentages reported in the CON application are consistent with these counts of agencies which participated in the telephone survey.

The table with population and computations at 1.5 per population requested in the Supplemental Letter is attached to this submittal as Attachment to Question #8. While this table uses the 1.5 factor, in reality this significantly understates the actual patient demand for home health services. As stated in the CON Application, actual historical utilization in the 25-county service area is 2.55 percent, which is more than 70 percent greater than the 1.5 percent guideline. Had the actual historical utilization been utilized to forecast the demand in 2018, the estimate of 24,300 visits in 2018 would have increased to 42,300 – 70 percent more than the computation utilized by the State to determine need presented in the attached table.

Actual utilization experience of all counties in the service area demonstrates the State's need formula of 1.5 percent of population is a dated formula not incorporating the healthcare system's focused initiative to provide healthcare services to patients in the least restrictive, least costly appropriate environment. Focus on community based programs and services, outpatient treatment and effectively treating patients in a less

June 20, 2014 12:06 pm

costly environment all contribute to the 1.5 guideline rate being an inappropriate measure of the need for home health services.

Coram's proposal involves providing services to approximately 228 patients per year which is but a very small fraction of the anticipated home health population.

In evaluating Decatur County population and utilization, factors that could contribute to its high home health use rate include but are not limited to the following: Decatur has the highest median age of any county in West Tennessee – and 21 percent greater than the overall area, the elderly (65+) percent is at 21.8 percent, 62 percent greater than the West Tennessee overall at 13.4 percent, and the old old (85+) is at 2.8 percent of population, 76 percent greater than the West Tennessee overall rate of 1.6 percent.

9. Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)

The applicant provided responses to the following standards but did not provide the required documentation. In addition, many of the letters provided appeared to be from the East TN Area (three MDs and two patients) which is not part of the proposed service area. If possible, please provide letters from physicians and patients representative of the proposed service area (not just metropolitan areas). Please provide the documentation requested in the following standards:

A. The applicant <u>shall</u> provide letters of intent from physicians and other referral sources pertaining to patient referral.

B. The applicant <u>shall</u> provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The letters from the various physicians and potential referral sources indicate support, but do not indicate the "projected number of cases by service category." Please provide the projected number of cases by service category by referral source.

The applicant has provided letters of support from one patient from the proposed service area experiencing difficulty, delay or inability to obtain the applicant's proposed services. If possible, please provide any additional letters from patients or providers located in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The number of licensed home health agencies in the proposed service area in the table on pages 50-51 is noted. However, it appears not all home health agencies are listed. Please contact Alecia Craighead, HSDA Statistical Analyst at 615-253-2782 to request a comprehensive listing and update the table on pages 50-51 and any other applicable tables.

June 20, 2014 12:06 pm

Please indicate the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The Applicant seeks a CON limited to providing nursing services incident to the delivery of infusion therapies in the home of its patients. All of the projected number of cases will be limited to nursing services incident to infusion therapies (i.e., preparation and cleaning of access site, administration of the infusion therapy, monitoring of the patient's vital signs and reaction to the therapy). These patients will generally not be provided skilled nursing services unrelated to infusion therapies. The Applicant is seeking additional letters of support from patients and providers and will supplement the record up to the hearing date upon receipt of additional letters of support.

Alecia Craighead provided an updated list of all home health agencies licensed in any of the 25 counties. That list is provided in the Attachment to Question #9 and identifies 62 such agencies. The utilization data presented in the CON application that identified home health agencies, included any home health agencies with 1 or more patients on 1 or more of the 25 counties, accounted for 61 agencies. While the list provided by Ms. Craighead includes one more home health agencies than the utilization chart in the CON application, this is due to the fact this additional agency had zero (0) patients in any of the 25 counties in the service area.

As noted in the CON application, 100 percent of the home health visits will be skilled nursing; and 100 percent of the skilled nursing home health visits will be infusion related. These would all be provided under physician orders and therefore the type of cases referred by physician.

10. Section C. Need, Item 1 (Specific Criteria: Home Health Services)- Item 6a and 6b

Your response is noted. Please clarify if the applicant intends to fully charge and file claims for HH infusion services.

Although the Applicant will not seek certification as a Medicare home health agency or enroll in as a home health agency in TennCare it will on occasion treat Medicare-covered and TennCare covered infusion patients. The Applicant will either bill these patients at the Applicant's self-pay rate private nursing visit, or, if the patients qualifies (which most TennCare patients do) apply the visit to the Applicant's charity care pool and bad debt policy. The vast majority of the Medicare/TennCare infusion patients that the Applicant will treat are not considered "home bound," a finding necessary to support billing those programs for home health services. The

June 20, 2014 12:06 pm

patient's infusion drugs and therapies are, however, covered by Medicare/TennCare and the Applicant's pharmacy bills those programs for those medications and therapies. The difficulties its patients and their primary care providers encounter in securing nursing services to support delivery of the infusion therapies in the home is not necessarily unique to Medicare/TennCare, but those programs do require the patient be considered home-bound in order to bill those programs. Thus, existing agencies typically will not see patients that are not home bound because the agencies cannot get paid. If the Applicant's CON is approved, it will see these non-home bound patients, and bill them at a self-pay rate for the nursing service, or apply the visit to the Applicant's charity care or bad debt policy.

11. Section C, Need, Item 3

Your response is noted. The application question asked the applicant to identify and justify the reasonableness of the proposed service area. Please provide the number of patients by patient county in the proposed 25 county service area of residence for the most recent year available at Coram Infusion.

The information requested is provided in the table in Attachment to Question #11. As noted in the table, approximately 86 percent of the Memphis branch's Tennessee patients reside within the defined service area. Those Tennesseans outside the service area primarily reside in Middle Tennessee and are transferred to the Nashville branch for necessary limited home health services and follow up.

In health planning, definition of a service area identifies those counties that will comprise the majority of the patient population. When services are provided to numerous counties within an area, occasionally counties are included in the definition that may have low population and therefore only sporadic patient needs but which are fully surrounded by the defined service area. As noted in the Attachment, a few low population counties in West Tennessee most recently had no patients but in years prior did, and at the same time are surrounded by counties with patients. Accordingly, it is reasonable to include all of those counties identified.

12. Section C, Need, Item 4.

Using current and projected population data from the Department of Health; and the most recent enrollee data from the Bureau of TennCare and demographic information from the US Census Bureau, complete the following table and include data for each county in your proposed service area.

June 20, 2014 12:06 pm

The information requested is provided in the Attachment to Question #12 table. The target population is those under the age of 65.

13. Section C, Need, Item 4.B

The applicant is forecasting 5% of its patients will be medically indigent. Please clarify if these patients would have TennCare, or qualify for TennCare benefits. Also, please clarify if the pharmacy component outside of the home health visits would also qualify as medically indigent for those proposed 5%.

In the previously approved similar application, CN1205-020, Coram Alternative Site Services, approved on September 26, 2012 forecasted 5% charity care. In the 2013 Coram Specialty Infusion Services Joint Annual Report for the period March 1, 2013 to June 30, 2013, the payment source reflected 100% commercial payment (\$133,325) representing 11 patients served. Please clarify why 5% charity care was forecasted in the application CN1205-020 but was not provided by Coram.

As noted above, with respect to indigent, Medicare or TennCare patients, the Applicant bills those patients at a self-pay rate for the nursing visit, and typically apply those sums owing to its charity care or bad debt policies. The Applicant does not separately track or break out sums not typically collected from private pay patients. The reason why only 11 commercial health patients were reflected in the Applicant's 2013 JARS Report is because that reporting period only reflected approximately 60-days of operations, and given short duration of operations and the small sample size it is not unusual that most patients would be commercial health patients. Moreover, even though the patients are enrolled as commercial health, in reality charity care or self-pay is often not identified until the patient has been on service for some time. It is believed that at least one of those 11 patients actually became a self-pay or charity care case.

14. Section C, Need, Item 6

The methodology of projecting the number of patients in Year One is unclear in the application. Please provide a brief simplified overview of the calculations, assumptions, referrals, etc. to project 207 patients in Year One.

The 207 patients identified in year one were based on a detailed analysis of the Memphis Branch patients by infusion therapy provided during calendar year 2013. First patients by quarter and year by therapy were identified. Next, the number of patients/therapies was estimated to increase by five percent per year to the limited home health agency's first year of operation. Then, by therapy, the following assumptions were applied:

June 20, 2014 12:06 pm

- Aralast patients were estimated to receive one visit per week for 1.5 hours.
- Chelation therapy patients were estimated to receive one visit at start of care for 2 hours.
- Chemotherapy patients were estimated to receive one visit per week for less than one hour.
- Fabrazyme patients were estimated to receive bi-weekly visits for 3 hours each.
- IVIG patients were estimated to receive an initial visit with then one visit per month for five hours per visit.
- IVIG subcutaneous patients were estimated to receive two to three visits at start of care, lasting 2 hours.
- Zemaira patients were estimated to receive one visit per week for 1.5 hours.
- Five percent of non-specialty patients (those not listed above) were estimated to have one visit per week for 2 hours.

Volumes were increased by five percent between years one and two, resulting in 228 patients in year two.

15. Section C. Economic Feasibility Item 1 (Project Cost Chart)

Your response is noted. However, please clarify if the leased space allocated to the proposed home health project has been accounted for on the Project Costs Chart.

The leased space is not separately denoted in the Project Cost Chart because the space that will house the proposed agency is unused space in the Applicant pharmacy's leasehold and there is no additional incremental cost associated with housing the agency in this space.

16. Section C. Economic Feasibility Item 4. (Historical Data Chart and Projected Data Chart)

Please clarify why the provision of charity care is 1% in the Year 2013 in the Historical Data Chart for the pharmacy operation, but the applicant is projecting 5% charity care on the Projected Data Chart.

The Historical Data Chart relates to the pharmacy operations; the Projected Data Chart is for the limited service home health agency. Because medically-necessary infusion services are typically covered by Medicare, TennCare and private health insurance the Applicant's pharmacy operations generally experience a low rate of charity care and bad debt. However, because the Applicant generally cannot bill Medicare, TennCare and some commercial health insurance for home health services incident to infusion therapy services because the patients are not "home bound," the Applicant will have to write-off more visits to its charity care and bad debt policies than it does with respect to the pharmacy. Hence the

June 20, 2014 12:06 pm

disparity between historical actual in the pharmacy and anticipated / projected in the home health agency.

17. Section C, Economic Feasibility, Item 9

Please complete the following chart for the proposed HHA.

Please see the following estimates for the supplemental requested information:

Payor	Year One Gross	% of Total		
<i>,</i>	Revenues	Revenues		
Medicare	\$0	0%		
Medicaid/TennCare	\$0	0%		
Commercial insurance	\$236,333	89%		
Self-Pay	\$15,933	6%		
Charity	\$13,277	5%		
Total	\$265,543	100%		

18. Section C, Economic Feasibility, Item 10

The Financial Statements are noted. Please provide the calculations the applicant used to derive the current ratio of 1:1.64.

The current ratio is derived by dividing current assets by current liabilities. The CVS 10K for calendar year 2013 current ratio of 1.64 is derived as follows: Current Assets of \$25,325,000,000 divided by Current Liabilities of \$15,425,000,000.

19. Section C, Contribution to Orderly Development, Item 1

Please address this question as a home health agency rather than a licensed pharmacy and resubmit.

Coram's proposed CON advances the orderly development of healthcare because incumbent HHA providers will not be impacted by Coram providing skilled nursing services incident to its infusion therapies. When a patient meets homebound status criteria, and thus qualifies for HHA nursing services, Coram first refers those cases to the incumbent, Medicare-certified agencies. Only when a certified agency cannot be located after contacting at least three area agencies, will Coram provide the nursing necessary to safely support medication administration to the patient. As noted elsewhere in this Application, the incumbent agencies do not accept non-homebound patients who do not qualify for HHA nursing

June 20, 2014 12:06 pm

services under Medicare or TennCare. Thus, none of the existing agencies reimbursable caseload is effected by Coram's proposed CON, yet patients who would otherwise be turned away by those agencies will be able to receive their infusion therapies in the safety and convenience of their home. Coram believes these factors, taken together, advance the orderly development of healthcare.

As a home health agency, orderly development will also be advanced because Coram will expand its service contracts to include limited nursing services with the following providers: Aetna, Blue Cross Blue Shield of Tennessee, Carecentrix, Cigna, Corizon, Coventry, Cover Tennessee, GEHA, Multiplan, HealthSprings of Tennessee, Magellan TennCare, Prime Healthcare, Medicare, St. Jude and TriCare. It will add other providers as warranted.

From a relationship standpoint with providers, Coram anticipates that between 80 and 90 percent of its patients will be referrals from physicians practicing at the following hospitals and/or those hospitals' discharge planners: St. Jude Children's Hospital, St. Francis Hospital, Vanderbilt University Medical Center, Methodist University Hospital, Methodist Germantown, Le Bonheur Children's Medical Center, Baptist Memorial – DeSoto, Baptist Memorial Hospital, Methodist North Hospital, Regional Medical Center, Select Specialty, and VA Medical Center. Because the Applicant's pharmacy has strong relationships with these providers, the Applicant will easily be recognized as a resource for patients who are not otherwise suited for the typical Medicare home health agency.

20. Section C, Contribution to Orderly Development, Item 3

Your response is noted. Please provide a comparison of the clinical staff salaries in the proposal to prevailing wage patterns in the service area either through comparison of the applicant's facility with similar previously approved projects within the primary service area, through the Tennessee Department of Labor & Workforce Development publications, or other published sources.

The only staff to be added for this proposed project are registered nurses. Comparison to actual salaries in the service area can be accomplished readily as Coram Memphis Branch pharmacy already employs a clinical nurse to work with the pharmacy patients. As shown in the table in the response to this question within the CON application, the current average existing salary for this employee is \$70,000. The Tennessee Department of Labor and Workforce Development publication for the Memphis MSA indicates LPN salaries range between \$33,730 and \$44,090 (25 to 75 percentile) and Healthcare Practitioners and Technical Workers, All Other

June 20, 2014 12:06 pm

\$36,990 (25th percentile) and \$67,520 (75th percentile). Because there is not a single category for registered nurses, we believe this latter category encompasses the RN position. Accordingly, given the existing pay rates at Coram Memphis Branch of \$70,000, and its proposed home health nursing salary of \$82,500, the amount proposed is reasonable and achievable.

21. Section C, Contribution to Orderly Development, Item 4

The applicant envisions that a pool between 8 and 15 per diem/per visit Certified Infusion Registered Nurses (CIRN) will be recruited from around the proposed 25 county larger population centers. Please clarify if this pool of nurses is accounted for in the Projected Data Chart in anticipated staffing pattern.

The pool of nurses is accounted for in the Projected Data Chart and the anticipated staffing patterns.

22. Section C, Contribution to Orderly Development, Item 7d

If possible, please provide the latest copy of the latest Coram Alternate Site Services, Inc.'s Nashville home health licensure survey.

The applicant is accredited by The Joint Commission. If approved, will this accreditation also include home health services?

The letter from The Joint Commission dated August 5, 2013 states home health services are already provided by Coram Healthcare and references the Memphis office. Please clarify.

Attachment to Question #22 is the latest licensure survey of the Nashville branch home health agency. If this CON application is approved, the accreditation by The Joint Commission will be extended to this limited service home health agency.

Reference in the accreditation document by The Joint Commission is the fact that the Memphis operation is accredited for services for which it is licensed. It is not currently accredited for home health. However, the certificate will be updated for limited service home health once the CON is approved and the Memphis branch is appropriately licensed.

23. Proof of Publication

Please provide copies of the publication of intent of the required 22 newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 25 county

SUPPLEMENTAL #1

June 20, 2014 12:06 pm

Phillip M. Earhart June 20, 2014 Page 17

proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

These are attached to this Supplemental submission.

With best regards,

HARWELL HOWARD HYNE GABBERT & MANNER, P.C.

Alix Coulter Cross

ACC/smb

June 20, 2014 12:06 pm

<u>AFFIDAVIT</u>

215

STATE OF COLORADO COUNTY OF DENVER

NAME OF FACILITY:

CORAM ALTERNATE SITE SERVICES, INC.

I, MICHAEL E. DELL, after first being duly sworn, state under oath that I am the Senior Vice President, General Counsel & Secretary of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that to the best of my knowledge, it is true, accurate, and complete.

Michael E. Dell

SVP, General Counsel & Secretary

Sworn to and subscribed before me, a Notary Public, this the 19th day of June, 2014, witness my hand at office in the County of Denver, State of Colorado.

PATRICIA V IVANCICH NOTARY PUBLIC STATE OF COLORADO NOTARY ID # 20034019486 MY COMMISSION EXPIRES JUNE 12, 2015

PATRICIA X IVANCICH

NOTARY PUBLIC

My commission expires June 12, 2015,

HF-0043

Revised 7/02

EXHIBIT A

SUPPLEMENTAL #1

June 20, 2014 12:06 pm

ATTACHMENT TO QUESTION #1
SUPPLEMENTAL REQUEST #1

SUPPLEMENTAL #1

June 20, 2014 12:06 pm

ATTACHMENT TO QUESTION #8
SUPPLEMENTAL REQUEST #1

County (A)	# Authorized Agencies* (B)	2014 Pop** (C)	Patients served 2013 (D)	Use Rate (Patient/1,000 pop) (E)	2018 Pop (F)	Projected Capacity (G)	Projected Need (H)	Additional Need (Surplus) for 2018 (G-H)
Benton	16	16,257	667	41.0	16,104	661	242	419
Carroll	16	28,119	1,246	44.3	27,831	1,233	417	816
Chester	15	17,472	563	32.2	17,999	580	270	310
Crockett	15	14,596	537	36.8	14,683	540	220	320
Decatur	17	11,822	638	54.0	12,080	652	181	471
Dyer	14	38,218	1,671	43.7	38,427	1,680	576	1,104
Fayette	30	40,930	713	17.4	44,888	782	673	109
Gibson	17	51,102	1,924	37.7	52,163	1,964	782	1,182
Hardeman	21	26,359	917	34.8	26,067	907	391	516
Hardin	17	26,012	1,157	44.5	26,244	1,167	394	774
Haywood	20	18,117	612	33.8	18,009	608	270	338
Henderson	15	28,186	1,015	36.0	28,631	1,031	429	602
Henry	15	32,697	1,283	39.2	32,956	1,293	494	799
Houston	16	8,388	281	33.5	8,447	283	127	156
Lake	8	9,732	325	33.4	9,468	316	142	174
Lauderdale	19	27,341	857	31.3	27,125	850	407	443
McNairy	17	26,582	1,089	41.0	27,299	1,118	409	709
Madison	20	99,555	3,121	31.3	101,001	3,166	1,515	1,651
Obion	14	31,453	1,280	40.7	31,222	1,271	468	802
Perry	14	8,014	258	32.2	8,096	261	121	139
Shelby	28	943,812	18,064	19.1	954,012	18,259	14,310	3,949
Stewart	12	13,549	339	25.0	13,941	349	209	140
Tipton	29	63,865	1,298	20.3	67,545	1,373	1,013	360
Wayne	12	16,854	640	38.0	16,724	635	251	384
Weakley	18	38,522	1,180	30.6	39,491	1,210	592	617
Total	44	1,637,554	41,675	25.4	1,660,453	42,190	24,907	17,283

^{*} The official population source used by HSDA is the TN Dept. of Health, Division of Health Statistics' Population Projections, 2010-2020

SUPPLEMENTAL #1

June 20, 2014 12:06 pm

ATTACHMENT TO QUESTION #11 SUPPLEMENTAL REQUEST #1

ATTACHMENT TO QUESTION #11, SUPPLEMENTAL REQUEST #1 Memphis Pharmacy Branch Patients, Tennessee Residents by Patient County

Patient County	Number of Patient Therapies	Percent of Total	Cumulative Percent of Total
Benton	62	2.5%	2.5%
Carroll	15	0.6%	3.0%
Chester	0	0.0%	3.0%
Crockett	0	0.0%	3.0%
Decatur	4	0.2%	3.2%
Dyer	59	2.3%	5.5%
Fayette	24	0.9%	6.5%
Gibson	25	1.0%	7.5%
Hardeman	42	1.7%	9.1%
Hardin	2	0.1%	9.2%
Haywood	9	0.4%	9.6%
Henderson	0	0.0%	9.6%
Henry	4	0.2%	9.7%
Houston	0	0.0%	9.7%
Lake	8	0.3%	10.0%
Lauderdale	32	1.3%	11.3%
McNairy	17	0.7%	12.0%
Madison	38	1.5%	13.5%
Obion	5	0.2%	13.7%
Perry	0	0.0%	13.7%
Shelby	1,705	67.4%	81.1%
Stewart	0	0.0%	81.1%
Tipton	96	3.8%	84.9%
Wayne	0	0.0%	84.9%
Weakley	21	0.8%	85.8%
Rest of Tennessee	360	14.2%	100.0%
Total Tennessee Patients	2,528	100.0%	

Source: Pharmacy Patient Analysis, Memphis Branch.

Note: Excludes out of State Residents who are provided pharmacy products from the Memphis Branch

ATTACHMENT TO QUESTION #12 SUPPLEMENTAL REQUEST #1

			-		_	_	_	_						-						_	_	_	_	_	_	
Persons Below Poverty Level as % of Total	20.4%	19.2%	16.9%	19.2%	20.9%	19.2%	13.2%	18.6%	23.0%	22.2%	21.2%	17.5%	17.4%	21.7%	30.3%	26.1%	23.5%	18.3%	17.1%	24.2%	20.2%	20.0%	14.0%	20.7%	20.5%	19.7%
Persons Below Poverty Level	l m	5,399	2,953	2,802	2,471	7,338	5,403	9,505	6,063	5,775	3,841	4,933	5,689	1,820	2,949	7,136	6,247	18,219	5,378	1,939	190,650	2,710	8,941	3,489	7,897	322,862
TennCare Enrollees as % of Total	20.9%	23.5%	19.2%	23.8%	20.8%	23.7%	14.1%	22.0%	23.1%	23.7%	28.8%	21.2%	21.0%	19.2%	20.0%	25.2%	25.2%	20.9%	20.8%	22.7%	24.0%	18.7%	18.0%	17.0%	16.8%	22.7%
TennCare Enrollees	3,392	6,621	3,347	3,473	2,458	9,065	5,784	11,238	6,085	6,171	5,224	5,983	6,882	1,614	1,948	6,899	069′9	20,841	6,545	1,819	226,651	2,530	11,514	2,864	6,458	372,096
Median Household Income	\$32,727	\$34,438	\$45,050	\$37,014	\$32,491	\$40,886	\$57,691	\$38,472	\$28,849	\$29,637	\$35,634	\$39,117	\$36,333	\$36,806	\$31,491	\$33,725	\$34,329	\$38,518	\$43,647	\$31,247	\$43,861	\$48,100	\$54,409	\$32,721	\$36,189	\$41,684
Median Age	46.4	42.3	36.8	39.9	44.8	39.7	42.8	40.1	39.5	44.7	39.6	40.1	45	42.6	38.1	36.9	42.4	37.2	42.1	43.7	35.1	43.9	37.1	41.6	36.9	37.1
Target Population- Projected Year as % of Total		79%	84%	82%	78%	82%	82%	82%	83%	78%	83%	82%	78%	79%	87%	85%	80%	84%	%08	%9/	87%	81%	%98	81%	84%	85%
Target Population-% change	-2.5%	-2.3%	2.4%	-0.1%	2.2%	-1.0%	8.2%	1.5%	-2.8%	-1.0%	-2.5%	-0.2%	-0.3%	78.6%	4.0%	-2.5%	1.5%	0.0%	-2.1%	-1.9%	-0.7%	1.7%	4.2%	-2.5%	1.8%	%0.0
*Target Population- Projected Year	12,240	22,059	15,073	12,039	9,446	31,626	36,763	42,952	21,517	20,412	14,968	23,399	25,680	6,687	8,250	22,931	21,834	85,163	24,987	6,187	829,066	11,226	58,178	13,505	33,273	1,409,461
*Target Population- Current Year (Under 65)	12,559	22,573	14,723	12,046	9,243	31,945	33,975	42,314	22,129	20,615	15,351	23,449	25,761	3,745	8,598	23,507	21,518	85,205	25,531	6,307	835,242	11,039	55,823	13,849	32,692	1,409,739
Total Population-% change	-0.9%	-1.0%	3.0%	%9.0	2.2%	0.5%	9.7%	2.1%	-1.1%	%6.0	%9:0-	1.6%	0.8%	0.7%	-2.7%	-0.8%	2.7%	1.5%	-0.7%	1.0%	1.1%	2.9%	5.8%	-0.8%	2.5%	1.4%
Total Population- Projected Year		27,831	17,999	14,683	12,080	38,427	44,888	52,163	26,067	26,244	18,009	28,631	32,956	8,447	9,468	27,125	27,299	101,001	31,222	8,096	954,012	13,941	67,545	16,724	39,491	1,660,453
Total Population- Current Year	16,257	28,119	17,472	14,596	11,822	38,218	40,930	51,102	26,359	26,012	18,117	28,186	32,697	8,388	9,732	27,341	26,582	99,555	31,453	8,014	943,812	13,549	63,865	16,854	38,522	1,637,554
Demographic Variable/ Geographic Area	Benton	Carroll	Chester	Crockett	Decatur	Dyer	Fayette	Gibson	Hardeman	Hardin	Haywood	Henderson	Henry	Houston	Lake	Lauderdale	McNairy	Madison	Obion	Perry	Shelby	Stewart	Tipton	Wayne	Weakley	Total

SUPPLEMENTAL #1

June 20, 2014

12:06 PHN TED: 01/31/2013 FORM APPROVED

	IT OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIE IDENTIFICATION NU	R/CLIA MBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING			SURVEY ETED
		TNHL225		B. WING		01/3	0/2013
NAME OF F	PROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY,	STATE, ZIP CODE		
CORAM	CORAM SPECIALTY INFUSION SERVICES 2970 SIDCO DRIVE NASHVILLE, TN 37204						
(X4) ID PREFIX TAG	REFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL			ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	DULD BE	(X5) COMPLETE DATE
H 001	1200-8-26 Initial. During the Initial Lic Coram Alternate Sit	ensure Survey cond e Services, on Janua	ucted at	H 001			
	2013, no deficiencie 1200-8-8 Standards Organizations.	s were cited under (Chapter				
			ST STEEL STATE OF THE STATE OF				

vision of Health Care Facilities

Division of Health Care Facilities

TITLE

(X8) DATE

IBORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TATE FORM

6899

MCZK11

If continuation sheet 1 of 1

SUPPLEMENTAL #1

June 20, 2014 12:06 pm

ATTACHMENT TO QUESTION #22 SUPPLEMENTAL REQUEST #1



STATE OF TENNESSEE DEPARTMENT OF HEALTH

OFFICE OF HEALTH LICENSURE AND REGULATION
EAST TENNESSEE REGION
5904 LYONS VIEW PIKE
KNOXVILLE, TENNESSEE 37919

February 4, 2013

Ms. Grace Chambliss, Administrator Coram Alternate Site Services, Inc. Attn: Licensure and Certification 555 17th Street, Suite 1500 Denver, CO 80202

Re: Coram Specialty Infusion Services, an Apria Healthcare Company

2970 Sidco Drive, Nashville, TN 37204-3715

Dear Ms. Chambliss:

The East Tennessee Regional Office conducted an initial licensure survey at your facility on January 30, 2013. As a result of the survey, no deficient practice was found.

If our office may be of assistance to you, please feel free to call (865) 588-5656.

Sincerely,

Karen B. Kirby, RN

Regional Administrator

Karen B. Kuluy

KBK/dt

Enclosure

COPY SUPPLEMENTAL-2

Coram Alternate Site Services CN1406-018



333 commerce street, suite 1500 nashville, tennessee 37201 phone: 615.256.0500 fax: 615.251.1059

h3gm.com



June 26, 2014

VIA HAND DELIVERY

Phillip M. Earhart
HSD Examiner
State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re:

Certificate of Need Application CN1406-018

Applicant's Response to Second Request for Supplemental Information

Dear Mr. Earhart:

We are in receipt of the Agency's Second Request for Supplemental Information. Please accept this as the Applicant's response to the same. Mr. Dell's Affidavit is attached hereto as Exhibit A.

1. Section C, Need, Item 6

The methodology of projecting 207 patients in Year One is noted. However, it remains unclear of the number of patients by therapy the applicant used in Year One and Year Two projections. Please complete the following table for Year One and Year Two projections:

Type of Patients	Brief Description of Service	# Year One	# Year Two Patients
		Patients	
Aralast [®]	Treatment for Alpha-1 antitrypsin deficiency ("Alpha-1"), chronic hereditary form of progressive emphysema. Aralast [®] is a Baxter Healthcare infusion therapy. Coram services include: Medication administration, patient teaching, starting and/or accessing/maintenance of IV access device and routine patient visit/assessment/vital signs and monitoring.	23	25

Phillip M. Earhart June 26, 2014 Page 2

Chelation	Administration of chemical binding agents, such as ethylene		
Therapy	diamine tetraacetic acid ("EDTA"), to remove heavy metals, such as iron, lead, mercury, cadmium, and zinc from the body. Preferred therapy for Coram patients is either Desferal [®] , a Novartis EDTA therapy, or Defroxamine [®] , a Fresenius-Kabi EDTA therapy. Coram services include: Medication administration, patient teaching, starting and/or accessing/maintenance of IV access device and routine patient visit/assessment/vital signs and monitoring.	1	1
Chemotherapy	Administration of anti-cancer drugs known as anti-metabolites. which interfere with cells making DNA and RNA, stopping the growth of cancer cells. Used in many cancer treatments, colon, rectum, and head and neck cancers. Due to in-home stability, preferred therapy for Coram patients is 5-FU fluorouracil sold as Adrucil®, a Fresenius-Kabi therapy. Coram services include: Medication administration, patient teaching, starting and/or accessing/maintenance of IV access device and routine patient visit/assessment/vital signs and monitoring.	0	0
Fabrazyme [®]	Enzyme replacement treatment for Fabry disease, a chronic hereditary and progressive deficiency of the Alpha-GAL enzyme. Fabrazyme® is a Genzyme therapy. Coram services include: Medication administration, patient teaching, starting and/or accessing/maintenance of IV access device and routine patient visit/assessment/vital signs and monitoring.	1	1
IVIG	Intravenous immunoglobulin (IVIG) is a blood product administered intravenously. It contains the pooled, polyvalent, IgG antibodies extracted from donor plasma for the treatment of chronic immune deficiencies, autoimmune disease and acute infections. Coram services include: Medication administration, patient teaching, starting and/or accessing/maintenance of IV access device and routine patient visit/assessment/vital signs and monitoring.	70	77
IVIG subcutaneous	Intravenous immunoglobulin (IVIG) is a blood product administered subcutaneously, which means under the skin. Coram services include: Patient teaching and assessments.	37	41
Zemaira [®]	Treatment for Alpha-1 antitrypsin deficiency ("Alpha-1"), chronic hereditary form of progressive emphysema. Zemaira® is a CSL Behring therapy. Coram services include: Medication administration, patient teaching, starting and/or accessing/maintenance of IV access device and routine patient visit/assessment/vital signs and monitoring.	33	36
Non-specialty	Treatment for all other patients including TPN, Antibiotics, Hydration Therapy, Multiple Sclerosis Injections, Opiate Management, Pain Management, Antiviral, Antiemetic, Fluid Replacement, etc. Coram services include: Medication administration, patient teaching, starting and/or accessing/maintenance of IV access device and routine patient visit/assessment/vital signs and monitoring.	42	47
Total		207	228

Phillip M. Earhart June 26, 2014 Page 3

2. Section C. Economic Feasibility Item 1 (Project Cost Chart)

Your response is noted. However, the unused leased space allocated to the proposed home health project will need to be accounted for in the Project Costs Chart. Please revise.

The Applicant did not include leasehold expenses because it is not incurring any incremental costs associated with its use of unused space in its leasehold. Nonetheless, the Applicant has allocated a pro rata portion of the leasehold expenses to the small space that will be used and noted such on the Project Cost Chart. Please see revised chart and assumption page attached. The amount allocated to leasehold costs was shifted from administrative cost, which included \$25,000 in contingency expense.

3. Proof of Publication

The applicant provided additional copies of the publication of intent required of newspapers of general circulation in the proposed service area. However, please submit the following missing proofs of publication:

Newspaper	Response
Brownsville State-Graphic	Did not publish
Dresden Enterprise	Attached
Humboldt Chronicle	Attached
The Courier	Requested
The Independent Appeal	Attached
The Leader	Requested
The Lexington Progress	Tear sheet attached - Affidavit requested
The News Leader	Requested
Lake County Banner Inc.	Attached
The Union City Daily	Requested
Messenger	

There was no publication in The Brownsville State Graphic. Affidavits have been requested for the other papers listed. Those that have been provided are attached or have been previously submitted. Some newspapers provided electronic tear sheets. Several of the newspapers have informed us that they are unable to provide affidavits at this time but will be forwarding to us as soon as possible. We will submit these upon receipt. The Commercial Appeal affidavit has been provided and is a newspaper of general circulation for all counties for which affidavits or tear sheets have not been provided including Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley. Tenn. AG Op. 06-127 (copy attached).

Phillip M. Earhart June 26, 2014 Page 4

With best regards,

HARWELL HOWARD HYNE GABBERT & MANNER, P.C.

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Alix Coulter Cross

ACC/smb

AFFIDAVIT

STATE OF COLORADO
COUNTY OF DENVER

NAME OF FACILITY:

CORAM ALTERNATE SITE SERVICES, INC.

I, MICHAEL E. DELL, after first being duly sworn, state under oath that I am the Senior Vice President, General Counsel & Secretary of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith (2nd Supplemental Request), and that to the best of my knowledge, it is true, accurate, and complete.

Michael E. Dell

SVP, General Counsel & Secretary

Sworn to and subscribed before me, a Notary Public, this the 25th day of June, 2014, witness my hand at office in the County of Denver, State of Colorado.

PATRICIA V IVANCICH NOTARY PUBLIC STATE OF COLORADO NOTARY ID # 20034019486 MY COMMISSION EXPIRES JUNE 12, 2016

ATRICIA V WANCICH

NOTARY PUBLIC

My commission expires June 12, 2015.

HF-0043

Revised 7/02



STATE OF TENNESSEE

OFFICE OF THE
ATTORNEY GENERAL
PO BOX 20207
NASHVILLE, TENNESSEE 37202

August 4, 2006

Opinion No. 06-127

Newspaper of General Circulation: The Commercial Appeal

OUESTION

Whether the Commercial Appeal, which has been published since 1840, qualifies as a "newspaper" or "newspaper of general circulation" for purposes of publication of official notices within the following Tennessee counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley.

OPINION

The Commercial Appeal qualifies as a "newspaper" or "newspaper of general circulation" for purposes of publication of official notices in all counties listed above, with the possible exceptions of Benton, Decatur and Henderson counties where the Commercial Appeal's availability is so limited that it may not be available in all parts of the county, as required by law.

ANALYSIS

With the exception of a definition in the Election Code, Tenn. Code Ann. §§ 2-1-101, et seq., the terms "newspaper" and "newspaper of general circulation" are not defined in state statutes that require publication of official notices in a "newspaper" or "newspaper of general circulation." Op. Tenn. Att'y Gen. 00-160 (October 17, 2000). The Election Code, however, does define the term "newspaper of general circulation" and lists the requirements for meeting that definition. The publication must bear a title or name, be regularly issued at least as frequently as once a week for a definite price, and have a second-class mailing privilege. It must be not less than four pages, be published continuously during the immediately preceding one-year period, and be published for the dissemination of news of general interest. Finally, it must be circulated generally in the political subdivision in which it is published and in which notice is to be given. Tenn. Code Ann. § 2-1-104(a)(13).

With respect to the statutes in which the terms "newspaper" or "newspaper of general circulation" are not defined, three criteria have been established in order for a publication to satisfy the requirements of those various statutes. First, the publication should be available in all parts of

Page 2

the county. Second, it should be published at least weekly. Third, it should contain news of general interest to the public. Op. Tenn. Att'y Gen. 04-064 (April 15, 2004).

These criteria are supported by the case of *Cook v. McCullough*, 1989 WL 155926 (Tenn. App. December 29, 1989); *p.t.a. denied* (1990). In that case, the Court of Appeals determined that The Nashville Record was a proper newspaper for purposes of Tenn. Code Ann. § 67-5-2502. The Court stated:

The Nashville Record is a "newspaper" within the sense of the applicable statute. It is published weekly. It is intended for circulation among the general public. It contains matters of general interest. It is in the form of a newspaper.

Cook v. McCullough, 1989 WL 155926 at 8.

We have looked at the May 10, 2006, issue of the Commercial Appeal ("issue" or "the paper"). Based on this issue, this Office notes that the Commercial Appeal is in a newspaper format with six multi-page sections: front page, local news, business, food, sports and classified advertisements. It is published in Memphis and is issued daily, at a single copy price of fifty cents (50¢) or a four-week subscription period price of \$17.25. The issue does not state the publication's founding date but states on its masthead, "166th Year."

The Commercial Appeal contains local, state, national and international news. Examples from the May 10 issue are these front page headlines: "Monster Truck," "Businesses Desperate as Crime Soars," "Parks Budget Closes Golf Course, 4 Pools," "Iranian's Sermon to Bush," "Hundreds of Schools Wipe Slate," and "Too Much Love for Majestic Orcas." The issue also includes display advertisements. The paper contains, then, news of general interest.

Information on page 2 of the May 10 issue shows that the Commercial Appeal is distributed to subscribers through home delivery and by mail, using "periodical postage" rates. The paper is also available for single-copy purchase at multiple locations in eighteen (18) counties: Carroll, Chester, Crockett, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley. Thus, the newspaper is intended for circulation among the general public, and based upon multiple single-copy purchase locations, should be available throughout the counties.

The Commercial Appeal's limited availability in Benton, Decatur and Henderson counties may mean that the newspaper may not be available throughout the county, as required by statute and case law. Benton County has three single purchase locations, all in the central part of the county. Because, however, Benton County has few cities, it may be that the three locations are sufficient. Decatur County has one single-copy purchase location, in Parsons. Decatur County has a population

¹ This Office has previously noted that "periodical postage" rate is the equivalent of "second class mailing privilege." Op. Tenn. Att'y Gen. 04-011 (February 3, 2004) at fn.1.

Page 3

of 11,629; Parsons' population is 2503.² Thus, Decatur County may have less than county-wide availability. Henderson County has three single-copy purchase locations, all in the Lexington area. Henderson County has a population of 25,733; Lexington has a population of 7393. Thus, Henderson County also may have insufficient countywide availability. This Office concludes that the question of whether the Commercial Appeal is available throughout these three counties for the purpose of publishing official notices is debatable.

Based on information you provided and on information gleaned from the May 10 issue, this Office has determined that the Commercial Appeal meets the general and statutory definitions of "newspaper" and/or "newspaper of general circulation" for purposes of publication of official notices in all counties listed in your question, with the possible exceptions of Benton, Decatur and Henderson.

PAUL G. SUMMERS Attorney General

MICHAEL E. MOORE Solicitor General

KATE EYLER Deputy Attorney General

Requested by:

The Honorable Mark Norris State Senator 304 War Memorial Bldg. Nashville, TN 37243

²All population figures used in this opinion come from the Tennessee Blue Book. *See* http://Tennessee.gov/sos/bluebook.



September 8, 2014

Melanie Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Coram CVS Specialty Infusion-Memphis, CN1406-018

Dear Ms. Hill:

Please be advised that Baptist Memorial Home Care is opposed to the certificate of need application referenced above because it does not meet the criteria for approval.

Representatives of Baptist Memorial Home Care will be present at the Agency's meeting scheduled for September 23, 2014, to explain more fully its objection to the proposal.

Thank you for your attention to this letter.

Sincerely,

Nancy Averwater

CEO Baptist Memorial Home Care, Inc.

Cc Alix Cross

Home Health Services Hospice Services Private Duty Services

June 13, 2014

Tennessee Health Services and Development Agency Andrew Jackson State Office Building 500 Deaderick Street, Suite 850 Nashville, Tennessee 37243

Re: Coram Alternate Site Service, Inc. d/b/a Coram CVS/Specialty Infusion Service

To Whom it May Concern:

I am writing on behalf of Tennessee Quality Homecare Northwest to express its opposition to the certificate of need application of Coram CVS/Specialty Infusion Services to add a limited service home health agency to provide and administer home infusion products and related infusion nursing services.

The reference certificate of need application does not meet the requirements of need, economic feasibility and contribution to the development of health care services. Tennessee Quality Homecare Northwest services the following counties: Benton, Carroll, Decatur, Gibson, Henderson, Henry, Houston, Madison, Obion, Perry, Stewart, and Weakley. Tennessee Quality Homecare Northwest could easily accommodate the patients that required nursing services related to infusion nursing.

Representatives of Tennessee Quality Homecare Northwest intend to be present during the Agency's consideration of this matter, in order to express its concerns in more detail.

Sincerely.

Bradley Todd, RN

Administrator

Tennessee Quality Homecare

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cc: Jeff Parrish, General Counsel Tennessee Health Management Trent Presley, Vice President of Operations Tennessee Quality Homecare

Home Health Services Hospice Services Private Duty Services

June 13, 2014

Tennessee Health Services and Development Agency Andrew Jackson State Office Building 500 Deaderick Street, Suite 850 Nashville, Tennessee 37243

Re: Coram Alternate Site Service, Inc. d/b/a Coram CVS/Specialty Infusion Service

To Whom it May Concern:

I am writing on behalf of Tennessee Quality Homecare Southwest to express its opposition to the certificate of need application of Coram CVS/Specialty Infusion Services to add a limited service home health agency to provide and administer home infusion products and related infusion nursing services.

The reference certificate of need application does not meet the requirements of need, economic feasibility and contribution to the development of health care services. Tennessee Quality Homecare Southwest services the following counties: Benton, Chester, Decatur, Hardin, Henderson, Madison, McNairy, Perry, Wayne. Tennessee Quality Homecare Southwest could easily accommodate the patients that required nursing services related to infusion nursing.

Representatives of Tennessee Quality Homecare Southwest intend to be present during the Agency's consideration of this matter, in order to express its concerns in more detail.

Sincerely,

Samantha Lineberry, RN

Administrator

Tennessee Quality Homecare

cc: Jeff Parrish, General Counsel Tennessee Health Management Trent Presley, Vice President of Operations Tennessee Quality Homecare



September 9, 2014

Melanie M. Hill, Executive Director Tennessee Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, TN 37243

It is my understanding that Coram Alternative Site Services, Inc. is seeking a Certificate of Need (CN1406-018) in the following counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, Madison, McNairy, Obion, Perry, Shelby, Stewart, Tipton, Wayne, and Weakley.

As a provider of home health care in several of these counties, I feel that the needs of the patients are met. We have had single case agreements with Coram and we have taken referrals from Coram and other infusion companies as needed over the years. As far as the first dose administration of medications, our company does not feel it is safe practice for any patient to receive any new intravenous medications in the home as a first dose. There are many unknowns associated with new meds and they are intensified when given intravenously. Our Agency has and does administer the IVIG and Alpha-1 Therapies such as Prolastin, Zemaira, and Aralast. As far as non-homebound patients, the Medicare Benefit Policy Manual, Chapter 7, states that the law requires that in order for a patient to receive home health services under Medicare part A and B, the patient must be confined to his or her home. We are already located in this rural West Tennessee area and we cover these rural counties efficiently. Also, we accept pediatric patients with high acuity levels, including but not limited to infusion services.

We hope that you respectfully decline this Certificate of Need in the above counties.

Sincerely,

Tiffany Stesmure, BSN, RN
Tiffany Fesmire, BSN, RN, Administrator

Volunteer Home Care of West Tennessee, Inc.

Parsons, TN



State of Tennessee **Health Services and Development Agency**

Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be publi	ished in the		ATTACHMEN		whic	ch is a new	spaper	
of general circulation in see ATT	'ACHMENT'	В	(Name of Newspare), Tennessee,	on or befor	e June (Mont	3,4,5 th/day)	, 20 <u>1,</u> 4 (Year)	
for one day.								
This is to provide official notice to t accordance with T.C.A. § 68-11-160 that:								
ram Alternate Site Services, Inc	c. d/b/a	Coram C	CVS/specialt	y Infusio	n Servic	es _{Home}	health	agen
(Name of Applicant)			 -	(Facility	Type-Existing)		11001011	agem
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			intends to file	an applica	tion for a C	Certificate o	f Need	
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last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

> **Health Services and Development Agency** Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency. HF51 (Revised 01/09/2013 – all forms prior to this date are obsolete)

ATTACHMENT A

f C I C'ay lating	Date of
Newspaper of General Circulation	Publication
Brownsville States-Graphic	5th
Buffalo River Review	4th
Carroll County News - Leader	4th
Chester County Independent	5th
Crockett County Times	4th
Dresden Enterprise	4th
Dyersburg State Gazette	5th
Humboldt Chronicle	4th
Lake County Banner Inc.	4th
The Camden Chronicle	5th
The Commercial Appeal	4th
The Courier	5th
The Independent Appeal	4th
The Jackson Sun	5th
The Lauderdale County Enterprise	5th
The Leader	5th
The Lexington Progress	4th
The News Leader	4th
The Paris Post-Intelligencer	4th
The Stewart-Houston Times	3rd
The Union City Daily Messenger	4th
Wayne County News	4th

ATTACHMENT B

County
Benton
Carroll
Chester
Crockett
Decatur
Dyer
Fayette
Gibson
Hardeman
Hardin
Haywood
Henderson
Henry
Houston
Lake
Lauderdale
Madison
McNairy
Obion
Perry
Shelby
Stewart
Tipton
Wayne
Weakley

ATTACHMENT C

To provide and administer home infusion products and related infusion nursing services ancillary to its pharmacy services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports within the following Tennessee counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, Madison, McNairy, Obion, Perry, Shelby, Stewart, Tipton, Wayne, and Weakley, from its current licensed home infusion pharmacy located at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee 38134 with an estimated project cost to not exceed \$98,000. Coram Alternate Site Services, Inc. is currently licensed in the following counties: Bedford, Bledsoe, Cannon, Cheatham, Clay, Coffee, Cumberland, Davidson, DeKalb, Dickson, Franklin, Giles, Grundy, Hamilton, Hickman, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Marion, Marshall, Maury, Montgomery, Overton, Putnam, Rhea, Robertson, Rutherford, Sequatchie, Smith, Sumner, Trousdale, Warren, White, Williamson, and Wilson.



(City)

State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

(Area Code / Phone Number)

PUBLICATION OF INTENT

The following shall be published in the "Legal Notices" section of the newspaper in a space no smaller than two (2) columns by two (2) inches.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in

accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, Home health agency Coram Alternate Site Services, Inc. d/b/a Coram CVS/ specialty Infusion Services (Facility Type-Existing) (Name of Applicant) owned by: CVS Caremark Corporation with an ownership type of intends to file an application for a Certificate of Need and to be managed by: see attached for iproject description begins here]: The anticipated date of filing the application is: Alix Coulter Cross The contact person for this project is (Contact Name) Harwell Howard Hyne Gabbert & Manner, PC 333 Commerce Street, Suite 1500 who may be reached at: (Company Name) (Address) Nashville

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

(State)

Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

HF50 (Revised 01/09/2013 – all forms prior to this date are obsolete)

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-3601 et seq., and the Rules of the Health Services and Development Agency, that Coram Alternate Site Services, Inc. d/b/a Coram CVS/ specialty Infusion Services, owned by CVS Caremark Corporation, with an ownership type of for profit corporation to be self-managed, intends to file an application for a Certificate of Need for the establishment of a limited service home health agency only to provide and administer home infusion products and related infusion nursing services ancillary to its pharmacy services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports within the following Tennessee counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, Madison, McNairy, Obion, Perry, Shelby, Stewart, Tipton, Wayne, and Weakley, from its current licensed home infusion pharmacy located at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee 38134 with an estimated project cost to not exceed \$98,000. Coram Alternate Site Services, Inc. is currently licensed in the following counties: Bedford, Bledsoe, Cannon, Cheatham, Clay, Coffee, Cumberland, Davidson, DeKalb, Dickson, Franklin, Giles, Grundy, Hamilton, Hickman, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Marion, Marshall, Maury, Montgomery, Overton, Putnam, Rhea, Robertson, Rutherford, Sequatchie, Smith, Sumner, Trousdale, Warren, White, Williamson, and Wilson.

The anticipated filing date of the application is June 6, 2014.

The contact person for this project is Alix Coulter Cross, Attorney, who may be reached at Harwell Howard Hyne Gabbert & Manner PC, 333 Commerce Street, Ste. 1500, Nashville, TN 37201, 615/256-0500.

Upon written request by interested parties a local fact-finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, Tennessee 37243

The published letter of intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

CERTIFICATE OF NEED REVIEWED BY THE DEPARTMENT OF HEALTH DIVISION OF POLICY, PLANNING AND ASSESSMENT

615-741-1954

DATE:

August 31, 2014

APPLICANT:

Coram Alternative Site Services, Inc.

d/b/a Coram CVS Specialty Infusion Services-Memphis

1680 Century Center Parkway, Suite 12

Memphis, Tennessee 38134

CON#:

CN1406-018

CONTACT PERSON:

Alix Coulter Cross, Esquire

Harwell Howard Hyne Gabbert and Manner

333 Commerce Street, Suite 1500 Nashville, Tennessee 37201

COST:

\$98,000

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The applicant, Coram Alternative Site Services, Inc., d/b/a Coram CVS/Specialty Infusion Services, located in Memphis (Shelby County), Tennessee, seeks Certificate of Need (CON) approval for the establishment of a limited service home health agency only to provide and administer home infusion products and related infusion nursing services ancillary to its pharmacy services, by way of example, and dressing changes on central lines and external access ports within the following Tennessee counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, Madison, McNairy, Obion, Perry, Shelby Stewart, Tipton, Wayne, and Weakley, from its current licensed home infusion pharmacy located at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee 38134.

The applicant is a wholly owned subsidiary of Coram Specialty Infusion Services, Inc., which has as its ultimate parent CVS Caremark Corporation, also a Delaware corporation. Coram's ultimate parent is controlled by executive officers and board of director. CVS is a publically traded stock corporation on the New York Stock Exchange (NYSE: CVS).

The total estimated cost for this project is \$98,000 and will be financed through cash reserves as attested to in a letter from the Senior Vice President, General Counsel, and Secretary located in Attachment C, Economic Feasibility, Item 2.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan.*

NEED:

The following chart illustrates the population projections for the applicant's 25-county service area.

Service Area Total Population Projections for 2014 and 2018

County	2014	2018	% Increase or
•	Population	Population	(Decrease)
Benton	16,257	16,104	-0.9%
Carroll	28,119	27,831	-1.0%
Chester	17,472	17,999	3.0%
Crockett	14,596	14,683	0.6%
Decatur	11,822	12,080	2.2%
Dyer	38,218	38,427	0.5%
Fayette	40,930	44,888	9.7%
Gibson	51,102	52,163	2.1%
Hardeman	26,359	26,067	-1.1%
Hardin	26,012	26,244	0.9%
Haywood	18,117	18,009	-0.6%
Henderson	28,186	28,631	1.6%
Henry	32,697	32,956	0.8%
Houston	8,388	8,447	0.7%
Lake	9,732	9,468	-2.7%
Lauderdale	27,341	27,125	-0.8%
Madison	99,555	101,001	1.5%
McNairy	26,582	27,299	2.7%
Obion	31,453	31,222	-0.7%
Perry	8,014	8,096	1.0%
Shelby	943,812	954,012	1.1%
Stewart	13,549	13,941	2.9-%
Tipton	63,865	67,545	5.8-%
Wayne	16,854	16,724	-0.8%
Weakley	38,522	39,491	2.5%
Total	1,637,554	1,660,453	1.4%

Source: Tennessee Population Projections 2000-2020, June 2013 Revision, Tennessee Department of Health, Division of Health Statistics

The following chart illustrates the Need/(Surplus) for the service area counties.

Home Health Patients and Need in Service Area # of 2018 **Projected** 1.5% of Need/(Surplus) County 2014 **Patients Agencies Population Served Population Capacity** 2018 2018 Serving **Population** Benton 10 16,315 667 16,104 658 242 (417)417 27,831 (812)Carroll 13 28,213 1,246 1,229 17,999 270 (314)Chester 13 17,355 563 584 (321)541 220 Crockett 12 14,568 537 14,683 638 12,080 655 181 (473)Decatur 14 11,773 576 (1,104)Dyer 10 38,205 1,671 38,427 1,681 23 40,081 713 44,888 799 673 (125)**Fayette** 14 50,748 1,924 52,163 1,978 782 (1,195)Gibson 917 902 391 (511)Hardeman 15 26,492 26,067 394 Hardin 14 25,968 1,157 26,244 1,169 (776)270 Haywood 13 18,199 612 18,009 606 (335)1,015 429 28,080 1,035 (605)Henderson 13 28,631 32,595 32,956 494 (803)Henry 10 1,283 1,297 8,358 8,447 284 127 (157)Houston 11 8,358 9,795 Lake 5 325 9,468 314 142 (172)Lauderdale 11 27,465 857 27,125 846 407 (440)3,121 15 99,153 101,001 3,179 1,515 (1,664)Madison 1089 27,299 1,126 409 (716)McNairy 13 26,408 468 Obion 12 31,536 1,280 31,222 1,267 (799)Perry 6 7,971 258 8,096 262 121 (141)Shelby 27 940,972 18,604 954,012 18,314 14,310 (4,004)

Stewart	10	13,436	339	13,941	352	209	(143)
Tipton	22	63,001	1,298	67,545	1,392	1,013	(378)
Wayne	9	16,887	640	16,724	634	251	(383)
Weakley	11	38,255	1,180	39,491	1,218	592	(626)
Total							(17,414)

Source: Tennessee Population Projections 2000-2020, June 2013 Revision, Tennessee Department of Health, Division Of Health Statistics and the Joint Annual Report of Home Health Agencies, 2013 (Final).

The applicant is seeking to establish a limited service home health agency, specifically to provide and administer home infusion products and related infusion nursing services. These services will be provided by a registered nurse who is appropriately credentialed and is certified with a CRNI designation (certified registered nurse infusion). Additionally, the applicant intends to provide the following skilled nursing services in conjunction with its home infusion therapy product; a) take and record vital signs; b) draw blood and other fluids for labs; c) treat any issues associated with the access site or port; d) change dressings associated with access points; e) administer the therapy or blood products; f) line maintenance; g) phlebotomy services; and h) infusion equipment and repair. These services and credentials are a unique service and not typical of the average Medicare certified home health agency available to West Tennesseans. The administrator of the home health agency will be the existing manager of the Memphis Branch and will be seamlessly added to the existing infrastructure of the Memphis Branch.

The applicant's nursing staff are specially trained in the art and skill of providing infusion therapies, most are certified, have over 1,600 hours of clinical infusion therapy experience, and have developed training and skills necessary to identify, collaborate, and treat therapy related effects, as well as communicate to patients on the proper care of catheter sites, sterile treatment, and monitoring of equipment and supplies.

According to the applicant, the types of patients will be restricted to infusion therapy patients. Types of infusion products to be administered include: antibiotics; total parenteral nutrition (TPN); hydration; cardiac products (such as inotropic therapies); intravenous immunoglobulin (IVIG) and other similar specialty drugs; pain management; antiemetic: and steroids. The types of patients served by Coram who have demonstrated needs for infusion nursing services from home which are otherwise unavailable from other home health agencies include the following:

- Specialty patients requiring IVIG and Alpha 1 therapies (IVIG is a plasma protein replacement for immune deficient patients who have decreased or abolished antibody production capabilities and Alpha 1 infusion therapy is given to treat the genetic disorder alpha 1 antitrypsin leading to decreased A1AT in the blood and lungs);
- First dose administration (First dose administration is the first time a prescribed infusion therapy is provided to the patient);
- Low intervention patients (a patient who is not homebound and does not require significant nursing intervention; rather they comprise a group of patients who are taught to self-administer thereby limiting the number of home skilled nursing visits;
- Three dose schedule patients and rural and pediatric patients (three dose patients are infusion patients whose therapy is administered three times throughout the day)
- Rural and Pediatric patients (rural patients are infusion therapy patients who reside well
 outside the major cities, and pediatric patients are children who require infusion therapy
 products and services).

According to the applicant, infusion nursing is highly specialized in protocol, equipment management, patient/family education training and time commitment. These aspects of home care delivery are not typical with the average Medicare certified home health agency patient profile

and delivery, or with their available nursing staff. Average Medicare certified home health agencies patient profile including documentation in the Joint Annual Report Summary has the following characteristics:

- Homebound;
- Average visit duration is one to two hours;
- Equipment usually is not involved;
- 80% of the visits are Medicare patients; and
- 71% are 65 years of age or older with nearly 50% being 75 or older

Infusion nursing patients, and those proposed to be served by Coram limited service home health agency, differ from the average Medicare certified home health agency patient. Notable differences are:

- The predominant age of the patient is under the age of 65;
- Private insurance is the dominant payor;
- Specialty patient infusion visits last up to six hours (one time per month for lengthy infusions of immunoglobin);
- Antibiotic therapy and TPN patients can have up to three doses (infusions) per day at eight hour intervals;
- Nurses require specialized understanding of and protocol for infusion equipment;
- The goal of infusion nursing is to train the patient to self-administer with limited follow up as needed by the nurse;
- The patient may not be homebound, but may not have reasonable geographic or financial
 access to reach an ambulatory infusion center, hospital, or other venue for infusion;
 Infusion therapy in the home is more cost effective to the system than accessing the
 product and service in an institution.

The needs of this high specific patient population with unique infusion therapy requirements is not being met in the most appropriate, accessible, and available means. With Coram's approval for a limited service home health agency license, these access problems can be ameliorated.

The applicant states the uniqueness of its patient population drives the need for Coram to be licensed as a home health agency. Approval of Coram's restricted home health license will enable a specific subset of the population to receive a higher standard of care in a lower cost environment, thereby contributing to the orderly development of health care while meeting a distinct patient and community need.

The applicant reports they have defined an unmet community need to provide home health services limited to infusion nursing and related services. The need for this service results from a lack of available or accessible home infusion nursing capabilities throughout West Tennessee. As a licensed pharmacy providing infusion therapy to patients in their homes, Coram is intimately familiar with the patients throughout the region and the hardships encountered by hospitals, physicians, and patients/families in effecting a timely discharge from the hospital when hospitalization is no longer required, but the patient and family have not initiated their first infusion dose nor are they knowledgeable about the process, the infusion equipment, and the specific

regimen which must be followed. Furthermore, as the pharmacy providing the infusion product to the patient, Coram's staff regularly meets with the patients and understands their skilled nursing needs, but is unable to assist in that regard as it does not have a home health license.

The applicant's encounter with a patient begins upon the patient's attending physician ordering an infusion or service and a referral is made to the applicant (either by the physician or discharge planners at area medical centers). The applicant verifies insurance, the physician order, and the patient's demographic information and transmits that data to the pharmacy which compounds the patient's drug therapy. Three groups within the applicant's organization then coordinate the patient's care: the pharmacy with respect to the drug mix, the courier service for secure and timely delivery, and nursing the education and administration. The applicant has implemented an electronic medical record system that securely communicates with the home office and summaries of care are shared with the patient's physician.

The applicant employs a director of nursing services who will be the supervisor for all the nursing functions associated with the applicant who will be available at all time during operating hour and shall participate in all activities relevant to the professional home health services provided, including the development of qualifications and assignment of personnel. In addition, the agency shall have a committee consisting of the nursing director, the agency's executive director, and the regional president who shall review at least annually past and present home health services to determine the appropriateness and effectiveness of the care provided.

According to the applicant, they are better able to meet this populations needs. This patient population's needs are not being met by incumbent home health providers, primarily because of reimbursement issues. They cannot get reimbursed for patients that are not home bound, they cannot get adequately reimbursed for infusion therapy that lasts several hours, and they only get reimbursed for one visit, even though three therapy regimens require three visits in the same day. Furthermore, the existing agencies will not treat patients on the first dose, and will not administer blood or blood products in the home. By granting the applicant's limited home health agency CON, these patients can remain in their home, thereby avoiding the time and inconvenience of traveling to an outpatient hospital clinic, as well as avoiding exposure of their immune suppressed bodies to nosocomial infections. Finally, care rendered by the applicant's certified infusion nurses is vastly superior to that of the RN untrained in spotting infusion complications, educating patients on the sterile site, and site maintenance.

The applicant projects 207 patients in year one and 228 patients in year two.

TENNCARE/MEDICARE ACCESS:

The applicant is a Medicare and Medicaid provider, certified as a pharmacy/DMEPOS. The applicant will not bill Medicare or Medicaid for Home Health Services.

The following chart provides a breakdown of payor sources for Year one of the project.

Total	\$265,543	100%
Charity	\$13,277	5%
Self-Pay	\$15,933	6%
Commercial Ins,	\$236,333	89%
Medicaid/TennCare	\$0	0%
Medicare	\$0	0%

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine they are mathematically accurate and the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located in Supplemental 2, page 74R. The total project cost is \$98,000.

Historical Data Chart: The Historical Data Chart for the existing Memphis location is located on page 80 of the application. The applicant reported 1,043, 966, and 820 patients in 2011, 2012, and 2013, respectively. The applicant reported net operating revenues of \$580,471, \$246,431, and \$119,353, each year, respectively.

Projected Data Chart: The Projected Data Chart for is located on page 82 of application. The applicant projects 207/1,775 patients/visits and 228/1,952 patients/visits in years one and two, respectively. The total net operating revenue in year one is projected to be \$482 and \$4,614 in years one two of the project.

The applicant provided the average charges, deductions, net charge, and net operating income below.

	Year One	Year Two
Average Gross Charge/Visit	\$150	\$157
Average Gross Charge/Patient	\$1,281	\$1,345
Contractual Allowance/Patient	\$141	\$148
Average Net Revenue/Patient	\$1,140	\$1,197
Average Net Revenue/Visit	\$133	\$140

The applicant states the only alternative to this proposal is maintaining the status quo. Maintaining the status quo in West Tennessee means continued longer stays in hospitals; more costly hospital stays; further hardships on patients and their families; inability to enhance quality of infusion therapy services in West Tennessee; operating in a more costly healthcare environment despite the industry's focus on enhancing quality and decreasing costs; and rejecting a true improvement in healthcare delivery at a lesser cost.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

Aside from payor relationships, the applicant has significant referral relationships with the existing hospital and provider community throughout the 25 county service area. The applicant provides a listing of these relationships on page 95 of the application.

The applicant states this proposal will not negatively impact existing home health providers as the services proposed will be very restricted and complement home health services provided by agencies throughout West Tennessee. Additionally, with Coram's intent to continue to train nurses at other home health agencies in the area of infusion, it is possible the quality of care in the overall home health community will increase.

Coram's restricted license will have a positive effect on existing institutional providers. Coram has a referral relationship for its infusion products with numerous West Tennessee hospitals and Vanderbilt University Medical Center. With the ability to have Coram's certified infusion nurses available for first dose protocol and training in a patient's home, patients will be discharged on a timelier basis from these area hospitals. The ultimate effect will be a decrease in patient costs across the continuum of the healthcare system.

According to the applicant, other benefits Coram believes will accrue to the community at large with its ability to provide infusion nursing services include but are not limited to the following:

- Less emergency room use;
- Better disease control;

- Fewer unscheduled physician office visits;
- Fewer total medications;
- Fewer hospitalizations;
- Better self and preventative care skills by the patient and family;
- Better drug compliance;
- Seamless delivery of care by infusion therapy provider;
- Certified infusion nurse able to provide hands on care in the patients home; and
- Skilled, experienced infusion staff able to teach the patient self-administration, compliance and safety.

Coram provides letters of support in Attachment C, Home Health Services, Item 5, the providers confirm the applicant's position that approving Coram's application to have a limited home health license will be a community benefit for patients, families, and providers.

The applicant sees no negative impact on the utilization of existing home health providers. This project will have a positive effect through more timely discharge and a cost savings for hospital referral sources and a positive effect on the home health community through enhanced quality care delivery in patient's homes.

The applicant will add 2.15 FTEs registered nurses to its existing staffing by year two of the project. Coram will place 1.0 FTEs CRNI in Memphis and maintain a pool of 8 to 15 per diem/per visit CRNIs located near the larger population centers throughout the service area.

Coram has educational and training relationships with David Lipscomb University, University of Tennessee, various home health agencies, physician offices in-services, hospital case managers and dietician in-services.

The applicant will be licensed with the Tennessee Department of Health, Board for Licensing Healthcare Facilities and accredited by The Joint Commission.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

Home Health Services

1. The need for home health agencies/services shall be determined on a county by county basis.

The applicant's 25 county service area is presented in the Need section of this report.

2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

Home Health Patients and Need in Service Area

County	# of Agencies Serving	2014 Population	Patients Served	2018 Population	Projected Capacity	1.5% of 2018 Population	Need/(Surplus) 2018
Benton	10	16,315	667	16,104	658	242	(417)
Carroll	13	28,213	1,246	27,831	1,229	417	(812)
Chester	13	17,355	563	17,999	584	270	(314)
Crockett	12	14,568	537	14,683	541	220	(321)
Decatur	14	11,773	638	12,080	655	181	(473)

Dyer	10	38,205	1,671	38,427	1,681	576	(1,104)
Fayette	23	40,081	713	44,888	799	673	(125)
Gibson	14	50,748	1,924	52,163	1,978	782	(1,195)
Hardeman	15	26,492	917	26,067	902	391	(511)
Hardin	14	25,968	1,157	26,244	1,169	394	(776)
Haywood	13	18,199	612	18,009	606	270	(335)
Henderson	13	28,080	1,015	28,631	1,035	429	(605)
Henry	10	32,595	1,283	32,956	1,297	494	(803)
Houston	11	8,358	8,358	8,447	284	127	(157)
Lake	5	9,795	325	9,468	314	142	(172)
Lauderdale	11	27,465	857	27,125	846	407	(440)
Madison	15	99,153	3,121	101,001	3,179	1,515	(1,664)
McNairy	13	26,408	1,807	27,299	1,126	409	(716)
Obion	12	31,536	1,280	31,222	1,267	468	(799)
Perry	6	7,971	258	8,096	262	121	(141)
Shelby	27	940,972	18,604	954,012	18,314	14,310	(4,004)
Stewart	10	123,436	339	13,941	352	209	(143)
Tipton	22	63,001	1,298	67,545	1,392	1,013	(378)
Wayne	9	16,887	640	16,724	634	251	(383)
Weakley	11	38,255	1,180	39,491	1,218	592	(626)
Total							(17,414)

Source: Tennessee Population Projections 2000-2020, June 2013 Revision, Tennessee Department of Health, Division Of Health Statistics and the Joint Annual Report of Home Health Agencies, 2013 (Final).

3. Using recognized population sources, projections for four years into the future will be used.

The service area population projections are located in the Need section of this report.

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Provided in 2 above.

Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

There is a surplus of 17,414.

- 5. Documentation from referral sources:
 - a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

Coram provides letters of support in Attachment C, Home Health Services, Item 5 providers confirm the applicant's position that approving Coram's application to have a limited home health license will be a community benefit for patients, families, and providers.

b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The applicant complies.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services. The applicant complies.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

The applicant complies.

- 6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
 - a. The average cost per visit by service category shall be listed.
 - b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The applicant provides these rates per county or region on page 58 of the application. The average cost per visit is projected to be \$133 in 2013.

The applicant will on occasion treat Medicare Covered and TennCare covered infusion patients. The applicant will either bill these patients at the applicant's self-pay rate private nursing visit, or if the patient qualifies for TennCare, apply to the applicant's charity pool and bad debt policy.